CULTURAL CONCEPTIONS OF RESEARCH

AND

INFORMED CONSENT

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DECLARATION

"Unless specifically indicated to the contrary, this thesis is the product of my own original work"

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ABSTRACT

AIDS has had a negative impact on developing countries. Because most developing countries cannot afford the new antiretroviral drug therapies, it has been suggested that preventive vaccines might reduce the spread of the HIV/AIDS epidemic (Bloom, 1998). The clinical trials of AIDS vaccines do, however, present with complex ethical issues such as informed consent. Informed consent is primarily grounded on the Western principle of respect for individuals as autonomous agents. This may be at variance, however, with African societies' emphasis on the social embeddedness of the individual.

The current study forms part of the HIVNET vaccine trials to be conducted in Hlabisa, in Northern Zululand, under the auspices of the South African Medical Research Council. The main aim of the study was to explore key informants' cultural conceptions of research and informed consent in order to facilitate community consultation and cultural sensitivity.

Maximum variation sampling was used to select twenty-three key informants, who are in leadership positions within Hlabisa. An interview guide was used to facilitate narrative disclosure of cultural conceptions of research and informed consent. Perceptions of research, conceptions of the informed consent process, and projected motivations for why individuals agree to participate in studies were explored during interviews.

Results suggest that members of the Hlabisa community have a limited understanding of the Western research process. Community education about research is therefore warranted. Informants indicated that community members would value the establishment of a relationship characterised by mutual respect for cultural differences between researchers and participants. This was perceived as likely to facilitate shared decision-making, and the reduction of the power differentials that exist between researchers and participants. While the involvement of key community leaders and family members was recommended by most informants, a few informants felt that participants could also make individual decisions about participation. The theoretical implications of the study are considered last.

1. INTRODUCTION

Experimental scientific studies were predominantly undertaken in developed countries in the past (Adityanjee, 1986). There has, however, been an increase in the conduct of research in the African context by Western researchers, mostly in response to the endemic nature of communicable diseases such as HIV/AIDS in developing countries. It has been estimated that sixteen thousand individuals are newly infected with the HIV virus daily (Bloom, 1998).

Since most developing countries cannot afford the antiretroviral drug therapies, vaccines are more likely to reduce the spread of the HIV/AIDS epidemic (ibid). As the pressure to find a vaccine mounts within the scientific community, Western researchers have turned to developing countries, especially those in sub-Saharan Africa, where large patient populations at risk for HIV infection can be identified and studied (Barry, 1992). Various agencies, such as the National Institutes of Health, have offered research funding with the aim of establishing collaborative studies into vaccines (ibid). The increase in the conduct of research within the African context, primarily by Western researchers, has contributed to the ongoing debate about the universal application of Western-derived ethical principles. Informed consent, an essential part of ethical principles, will be the focus of this study.

Informed consent has become an issue of paramount importance, primarily because of the cross-cultural nature of much research. The Western principle of informed consent is based on the notion of respect for persons as autonomous agents (Christakis, 1988; Gostin, 1995). This is at variance, however, with more relational notions of personhood found in other societies such as in Africa, which emphasise the embeddedness of the individual within society, and define a person by his or her relationships with others (Christakis, 1988).

Several authors (Adityanjee, 1986; Angell, 1992; Barry, 1992; Christakis, 1988,1992; Ijsselmuiden & Faden, 1992) have commented on the need for cultural differences to be taken into consideration when research is conducted in non-Western contexts. There is, however, an ongoing debate about the cross-cultural application of ethical principles. The universalist school of thought recommends the uniform application of ethical principles and states that

"ethical implications of research involving human subjects are identical in principle wherever the work is undertaken" (Council for International Organisations of Medical Sciences, 1982 in Christakis, 1988, p.142). The relativist school of thought states that "...moral values, including human rights are relative to the cultural context in which they arise" (Donoho, 1991). This ongoing debate appears to have complicated the issue of what is regarded as ethically appropriate for cross-cultural research.

There appears to be a dearth of literature on African conceptions of ethical principles such as informed consent. The limited South African literature on informed consent has predominantly covered the medical setting, HIV testing, the legal context; with less focus on the research process (Henley, Benatar, & Robertson, 1995). This study been substantially informed by literature from the Western world as more has been written on informed consent from that context. There is very little literature on cultural conceptions of informed consent and research, although there is general consensus that there are cross-cultural differences that could, and likely do, influence the informed consent process as generally conducted in Western contexts.

It therefore seemed necessary to closely examine the conceptions of research and informed consent held in a local community. The current study forms part of the HIV Network Prevention Trials (HIVNET). The HIVNET vaccine trials will be conducted at Hlabisa, a district in northern KwaZulu-Natal, under the auspices of the South African Medical Research Council. The trials are funded by the National Institutes of Health in the United States of America. It is planned that women, aged 16-30 years, whose male partners are migrant workers, will be selected for participation in vaginal microbicide and future HIV vaccine trials. This group has been selected because the HIV incidence and prevalence rates among them are increasing at a very rapid rate (Gilks, Haran, & Wilkinson, 1996).

The informed consent of prospective research participants has been identified as a fundamental aspect of HIVNET, due to the nature of the research and the necessity to uphold and respect human rights. HIV vaccine trials present significant medical and social risks for participants (Richter, Lindegger, Abdool Karim, & Gasa, 1999). Participation in vaccine trials

may cause vaccine-induced seropositivity which has social implications. Exposure to a vaccine may enhance disease if the participant is subsequently exposed to HIV, and may also affect his or her capacity, as a consequence of immune tolerance, to receive a more effective vaccine developed in the future. The social risks of participation include confidentiality issues, stigma, occupational and social constraints, violence and abandonment, and much more. Informed consent procedures are particularly important for vaccine trials to ensure that prospective participants understand both the nature of the study and its risks and benefits (ibid).

There are indications, as suggested above, that an informed consent process which is informed by Western principles, may not be suitable for an African context such as Hlabisa, which is likely to adhere to different social and moral principles. The current study explored twenty-three key informants' cultural conceptions of research and informed consent in preparation for the HIVNET project outlined above.

It was thought that interviewing key informants in leadership positions would prove informative as they are in contact with Hlabisa people, and are thus more likely to be informed about their beliefs. An interview guide was used to facilitate narrative disclosure of conceptions of research and informed consent. The guide was designed to explore informants' perceptions of research, conceptions of informed consent and projected motivations for why people agree to participate in research. The aims and objectives of the study are presented after the literature review.

2. LITERATURE REVIEW

2.1 INFORMED CONSENT

Various definitions of informed consent have been offered (Locke, Spirduso, & Silverman, 1993; Meisel & Kuczewski, 1996; Shore, 1995). These definitions tend to focus on the different components of informed consent which will be presented in a later section. There are few definitions that encompass all the components of informed consent. A broad definition of the informed consent process is presented in this section. An attempt is made to integrate various definitions of informed consent in order to illuminate the various components of informed consent.

2.1.1 Definition

Informed consent is a process whereby prospective research participants are informed about the general nature of the investigation and about their expected role in terms of time and effort (Locke et al, 1993). Prospective participants are also informed, during this process, about the benefits they will receive for participating in the study. They are given an outline of the "reasonably foreseeable risks and discomforts" of the research investigation (Federal Regulations, 1974 in Shore, 1996, p.7). If physical or psychological risks are more than minimal, prospective participants are informed about procedures that will be followed to protect their well-being (Locke et al, 1993).

Participants' freedom to withdraw at any time without any negative repercussions is an essential part of the informed consent process (Dorn, Susman, & Fletcher, 1995). Prospective participants should be informed of the procedures to be used to ensure that their anonymity is protected. Locke et al (1993) recommend that it be made clear that anonymity cannot be guaranteed, but that rigorous procedures will be followed to ensure that participants are protected. Locke et al add that participants should be provided with the name of the person responsible for the study, to whom they can direct questions related to their participation, and the consequences thereof. They also recommend that participants be offered the opportunity to receive feedback about the results of the study.

Shore (1996) adds that all the information given to prospective research participants must be provided in an understandable language, and participants must be given adequate time to decide whether to participate or not. Participants must be competent to appreciate the risks and the benefits expected from the study (Ho, 1995; Parker, 1995). After the transmission of information about the study, prospective participants are then asked to give their consent to participate in all aspects of the investigation.

Some authors have stated that five conditions need to be met for consent to be "informed", "real" or "valid" (Benatar, 1992; Kent, 1996; Meisel & Roth, 1983): 1) information that is material to decision-making must be transmitted to the prospective participants, 2)participants' understanding of the transmitted information is essential, 3) the decision that the participant makes must be arrived at without undue pressure or coercion, 4) competence, which Meisel and Roth (1983) describe as the legal presumption that participants have the capacity to comprehend the information disclosed, is also essential, 5) the prospective participant must actually decide whether to accept or refuse to give consent to participate in a research study.

It remains questionable, however, whether these conditions of informed consent are met in practice. The conditions do, however, reflect what the informed consent process should involve for it to be considered valid.

2.1.2 Historical background of informed consent

Faden and Beauchamp (1986) suggest that the formal requirements of informed consent primarily emerged from two contexts: the ethical standards governing clinical medicine, and the standards governing research with human participants. Although the conduct of research with human participants is almost as ancient as medicine itself, concern about the protection of research participants is a fairly recent phenomenon. The development of informed consent within the research setting is explored in this section.

a)The Nuremberg Code of 1947

The origins of formal ethical standards for the guidance and control of research are traced to abuses of war prisoners by Nazi physicians and researchers during the Second World War (Kimmel, 1996). The Nazis conducted horrific experiments which involved the observation of healthy prisoners' reactions to various diseases, the course of infections, and treatment for experimentally inflicted wounds. Nazi physicians and researchers were tried during the Nuremberg trials.

The Nuremberg Code of ethics was an important outcome of the Nuremberg trials. It was formulated with the intention of preventing future atrocities such as those that had been conducted by Nazi researchers under the pretext of medical science. The Code was not designed to prescribe investigation as such, but to outline permissible limits for experimentation.

Katz (1972, in Kimmel, 1996, p.30) provides a summary of the ten principles of the Nuremberg Code:

1. The voluntary consent of the human subject is absolutely essential.
2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other means of study, and not random and unnecessary in nature.
3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.
4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.
5. No experiment should be conducted where there is an *a priori* reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.
6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.
8. The experiment should be conducted only by scientifically qualified persons.
9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical and mental state where continuation of the experiment seems to him to be impossible.
10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

Informed consent is therefore presented as an essential feature of the Code. Faden and Beauchamp (1986) suggest that the Code requires that consent have at least four characteristics: it must be voluntary, competent, informed, and comprehending. The Code does not, however, attempt to describe how the participant's consent may be secured or how the limits of experimental risks are to be defined, because the Nuremberg Court held that these were beyond its sphere of competence.

Christakis (1992) states that the Code rapidly became recognized as an authoritative, international statement of the rights of research participants, partly because those that developed the Code aspired to a natural, universal law to which all individuals could be held accountable, above the specific laws of the jurisdiction under which the criminal behaviour occurred. It remains open, however, whether the autonomy of the individual, which is implied in the Code, is a principle that is upheld universally.

Kimmel (1996) argues that the existence of ethical codes is no guarantee that research abuses will be prevented. Despite the public outcry regarding the Nazi experiments and the subsequent development of the Nuremberg Code, researchers continued to conduct unethical experiments that indicated that the concept of informed consent was being disregarded. The Tuskegee syphilis study, for example, was initiated in 1932 by the U.S. Public Health Service and continued for forty years. Its purpose was to study the natural history of untreated

syphilis. The subjects were poor black men from Alabama who had the disease but were neither given the standard treatment for the disease when it became available, nor told the truth about their participation in the study (Levine, 1991). This study, and numerous others, indicate that ethical codes can only provide limited protection (ibid).

Ethical codes do, however, serve certain useful functions, such as defining the grounds by which a particular research procedure can be assessed as morally right or wrong in terms of the value judgements that have been codified in formal documents (Kimmel, 1996). The Nuremberg Code, for example, offered some degree of protection to research participants by attempting to provide a legal framework that would justify research involving human participants on condition that it was "within reasonable, well-defined bounds and satisfied certain moral, ethical, and legal concepts" (Christakis, 1992, p.1085).

The Code also stimulated ethical codification in various research disciplines, including the behavioural sciences (Kimmel, 1996) and medicine (Faden & Beauchamp, 1986). Faden and Beauchamp contend that the Code was, however limited in scope, and was soon perceived as inadequate to govern the complete variety of situations arising in the expanding fields of biomedical and social scientific research. Pressure for the development of more specific guidelines for different fields began to increase (ibid).

b) The Declaration of Helsinki of 1964

The gross violations of human rights investigated at Nuremberg were gradually perceived by the medical community as a general threat to the reputation and integrity of biomedical research. The World Medical Assembly thus began to draft a more suitable code in the early 1960s to distinguish ethical from unethical clinical research (Faden & Beauchamp, 1986). The Declaration of Helsinki was adopted by the eighteenth World Medical Assembly in Helsinki, Finland in 1964, with the intention of guiding the conduct of biomedical research. The Declaration was revised in Tokyo, Japan in 1975, in Venice, Italy in 1983, and in Hong Kong in 1989.

The basic principles of the Declaration are divided into three sections: the professional conduct of medical practitioners, the protection of participants, and informed consent. The sections are discussed below:

Professional conduct

The Declaration states that biomedical research with human participants conform to generally accepted scientific principles and be based on a thorough knowledge of the scientific literature. The design of each experimental procedure should be clearly formulated in a protocol, which should be presented for guidance to a specially appointed committee that is independent of the investigator and the sponsor. This committee should be in conformity with the laws of the country in which the research experiment is being performed.

Protection of participants

Biomedical research should be conducted only by scientifically qualified persons. It should be preceded by a careful assessment of predictable risks in comparison with foreseeable benefits to the participants. Research should not be conducted unless there is satisfaction that the hazards are believed to be predictable. It should be terminated if the hazards are found to outweigh the potential benefits. Concern for the interests of the subjects must always prevail over the interests of science and society. Every precaution should be taken to respect the privacy of the participants. The physician is obliged to preserve the accuracy of the results in the event of publication.

Informed consent

Each prospective participant must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study. He or she should be informed of the freedom to withdraw from participation at any time, without negative repercussions. The physician should then obtain the participants' informed consent. Informed consent should be obtained by a physician who is not engaged in the investigation, if there is reason to believe that the participant is in a dependent relationship with the researcher/physician. In the case of legal incompetence, in the form of physical or mental incapacity, consent should be obtained from a legal guardian in accordance with national legislation.

Faden and Beauchamp (1986) contend that the Declaration will be remembered as a foundational document as it is indicative of self-regulation internal to medicine itself. The Declaration of Helsinki, like the Nuremberg Code, made consent a central requirement of ethical research. It also made mention of the power differentials that often exist in the research setting. Because the autonomy of the individual is also implied in the Declaration, concerns about its cross-cultural application remain unanswered.

c) Belmont Report of 1979

The Belmont Report is a product of the debate on federal policies in the US whose objective was the protection of human research participants. The fundamental justification for requiring informed consent from human participants as a matter of U.S. public policy is thus best stated in the Report (1979).

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. The Report made the protection of the autonomy and personal dignity of research subjects the focus of the informed consent process. The Belmont Report states that the basic ethical principles are respect for persons, beneficence, and justice:

Respect for Persons

The Report states that individuals should be treated as autonomous agents, and persons with diminished autonomy such as those with mental disability, or circumstances that severely restrict liberty; are entitled to protection.

Beneficence

The two general rules of beneficence are: firstly, do no harm and secondly, maximize possible benefits and minimize possible harms.

Justice

This principle addresses questions of "fairness in distribution" or "what is deserved". An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.

Informed consent is presented as one of the applications of research. The report suggests that the consent process contains three elements: information, comprehension, and voluntariness. The assessment of risks and benefits is also discussed as another application. The Report alludes to the challenges likely to be faced in balancing the risks and benefits of research, but asserts that the risks and benefits affecting the immediate research subject are far more important than those affecting society. It indicates, however, that interests other than those of the subject may be sufficient to justify the risks involved in the research, provided the subject's rights have been protected. The Report can be described as the first ethical standard that acknowledged that it might prove challenging to uphold the interests of the individual over those of the society. This is suggestive of an awareness that individuals are not completely autonomous.

d) Guidelines of the Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organisation (WHO) of 1993

Christakis (1992) suggests that the Nuremberg Code and the Declaration of Helsinki assumed an aura of universality and were then applied to a wide variety of culturally, clinically, and economically specific settings. There was a gradual realisation, however, that these codifications might not be appropriate for use with cultures that emphasize the social embeddedness of an individual, rather than his or her autonomy from society.

The Council for International Organizations of Medical Sciences (CIOMS) and the World Health Organization (WHO) jointly developed and published the *Proposed International Guidelines for Biomedical Research Involving Human Subjects* in 1982. The purpose of the Guidelines was to indicate how the fundamental ethical principles presented in the World Medical Assembly Association's Declaration of Helsinki, could be applied effectively, particularly in developing countries, by taking culture, socioeconomic circumstances, national

laws, and executive and administrative arrangements into consideration (CIOMS & WHO, 1982).

The *Proposed Guidelines* were extensively distributed and widely used throughout the world (CIOMS & WHO, 1993). Christakis (1992) contends that the guidelines have emerged as the leading articulation of ethical standards specifically for transcultural research. A survey conducted on the use of the guidelines indicated that most respondents felt that the guidelines should be reviewed with particular reference to the ethical issues of large-scale trials of vaccines and drugs, transnational research, and experimentation involving vulnerable population groups (CIOMS & WHO, 1993). This was in response to the HIV/AIDS epidemic and the increasing conduct of preventive vaccine trials which raised ethical issues that had not been foreseen when both the Declaration of Helsinki and the CIOMS Guidelines of 1982 had been formulated.

Extensive collaboration by the CIOMS and the WHO resulted in *International Guidelines for Ethical Review of Epidemiological Studies,* published in 1993 (ibid). These guidelines reflect ethical concerns for the protection of the rights and welfare of research participants and of vulnerable prospective participants. Vulnerability is defined as a substantial incapacity to protect one's own interests owing to a lack of alternative means of obtaining medical care, lack of capability to give informed consent, or being a junior or subordinate member of a hierarchical group.

Although there are fifteen CIOMS guidelines in the 1993 document, only those guidelines that are applicable to the current study will be outlined below:

Guideline 1

The investigator must obtain the informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the proxy consent of a properly authorized representative.

Guideline 2

The investigator must provide the individual with information about the study, in a language that he or she is capable of understanding.

Guideline 3

The investigator has a responsibility to ensure that the rights and welfare of participants are protected.

Guideline 4

Payment and free medical services may be necessary, but should not be so extensive that they induce prospective participants to participate against their better judgement.

Guideline 8

Before undertaking research in underdeveloped communities, the investigator must ensure, among other things, that every effort will be made to ensure that the consent of individual participants is informed, and that the proposals for the research have been reviewed and approved by an ethical committee that includes consultants who are thoroughly familiar with the customs and traditions of the community.

Guideline 9

Individual informed consent may be inadvisable for epidemiological studies, and the ethical review committee should be consulted where this applies.

Guideline 10

The selection of participants must facilitate the equitable distribution of burdens and benefits of research. The rights and welfare of vulnerable individuals must be strictly protected.

Guideline 12

The investigator must ensure the confidentiality of research information, and inform participants of limits thereof.

Guideline 13

Participants are entitled to financial compensation or other assistance if they suffer physical injury as a result of participation.

Guideline 14

The investigator's proposals to conduct research must be reviewed and approved by one or more independent ethical and scientific review committees before research begins.

Guideline 15

An external sponsoring agency must first obtain ethical approval in its own country, and then obtain ethical approval in the host country before the conduct of research.

Christakis (1992) contends that there is a tension in the guidelines between a desire for culturally relevant application of ethical principles on the one hand and, on the other hand, the belief that "the ethical implications of research involving human subjects are identical in principle wherever the work is undertaken" (ibid).

There are indications that the Nuremberg Code provided a broad framework for the protection of human research participants in the conduct of research. The subsequent codifications developed were attempts to adapt some components of informed consent for specific use within certain fields. Later codifications attempted, for example, to address issues such as proxy consent that had not been addressed within the Nuremberg Code. The legal and moral foundations of informed consent are discussed below.

2.1.3 Foundations in legal theory

Faden and Beauchamp (1986) suggest that informed consent has its foundations in multiple disciplines and social contexts such as the health professions, law, the social and behavioural sciences, and moral philosophy. They assert that the most influential fields are law and moral philosophy, possibly because the central challenges of informed consent have mostly been framed in these fields. Informed consent can thus be understood in terms of two different

senses: the legal and the moral sense, with different implications for each. The legal sense of informed consent will be discussed first.

Benatar (1992) suggests that the legal sense is most commonly aimed for in practice. This point of view states that a researcher has a duty to inform the participant about the study and obtain his or her consent. Informed consent in this sense thus implies that the participant has substantial understanding of the procedures and its implications, and has given his or her consent without undue influence of others, and that the consent procedure meets with legal and institutional policy requirements (ibid). Should a participant be injured as a result of a failure of the researcher to disclose adequate information about the investigation, then the participant may sue for damages from the researcher (Faden & Beauchamp, 1986; Lantos, 1993).

Although the participant has the right to consent or refuse any intervention, the focus tends to be on the researcher, who has the duty to inform and who risks liability should she or he not fulfill obligations. This legal vision tends to place more emphasis on financial compensation for unfortunate research outcomes than on either disclosure of information or the consent of the participant in general (Faden & Beauchamp, 1986). The legal sense of informed consent can also be described as primarily focussing on indemnity for researchers than on the shared decision-making that is essential for informed consent, since it seems to be geared towards the protection of the researcher. Benatar (1992) contends that this sense of informed consent is legalistic, minimalist and somewhat defensive, and fails to meet the second and more important moral sense of informed consent.

2.1.4 Foundations in moral theory

The shortcomings of the legal sense of informed consent outlined above have resulted in suspicions about the adequacy of the law for setting requirements for informed consent. Suggestions have been made that the major issues in informed consent are moral rather than legal. Benatar (1992) suggests that the moral sense of informed consent is based on individual self-determination during which open communication promotes deeper understanding of the issues involved. There is mutual trust and shared decision-making.

Faden and Beauchamp (1986) suggest that the moral sense of informed consent has less to do with the liability of professionals as agents of disclosure, and more to do with the autonomous choices of participants. This sense arises from the principle of respect for autonomy, which focuses on the participant, who has a right to make an autonomous choice.

There are three moral principles that are relevant to informed consent since they provide the basis for the more specific rules and requirements found in the professional codes of medical and research ethics (Faden and Beauchamp, 1986). These are: respect for autonomy, beneficence, and justice. A discussion of the moral principles follows:

Respect for Autonomy

Faden and Beauchamp (1986) state that this principle is rooted in the liberal Western tradition of the importance of individual freedom and choice, both for personal development and political life. Personal autonomy can thus be defined as personal governance, which involves personal rule of the self by adequate understanding while remaining free from controlling interferences by other people. Autonomy also involves accepting responsibility for one's choices (ibid).

Beneficence

The principle of beneficence emphasises the following elements, which are linked through the common theme of promoting the welfare of others: one ought not to inflict evil or harm, one ought to prevent evil or harm, one ought to remove evil or harm, and one ought to do or promote good (ibid). The principle of beneficence has its foundations in this principle: "above all, do no harm". It thus challenges researchers to constantly weigh the risks of harm presented by interventions against possible benefits for participants or public interest.

Justice

The principle of justice highlights the importance of treating people according to what is fair, due, or owed (Faden and Beauchamp, 1986). Faden and Beauchamp suggest that any denial of a good, or piece of information to which a person has a right or entitlement by virtue of their participation constitutes an injustice. The involvement of vulnerable participants such as

the economically disadvantaged, due to their ready availability constitutes injustice, mostly because it is often easy to manipulate such subjects because of their socio-economic condition.

The moral and legal senses of informed consent outlined above provide a useful insight into informed consent. Both senses highlight, however, the fact that informed consent has its foundation in the principles of individualism and freedom which have flourished in the Anglo-American world (Benatar, 1992). Benatar adds that informed consent was determined by growing concern with, and emphasis on, human rights, as well as specific concerns with regard to the motives of researchers while conducting research on human beings. This emphasis on human rights has resulted in the dominance of the principle of autonomy as the fundamental basis for informed consent. Henley et al (1995) suggest that South Africa, like most developed countries, recognises participants' rights to self-determination.

This dominance of respect for the autonomy of the individual has resulted in concerns about the applicability of informed consent in societies that tend to emphasise relatedness rather than individualism (Adityanjee, 1986; Barry, 1992, Christakis, 1988; 1992). Faden and Beauchamp (1986) suggest, for example, that morality is:

> ...concerned with practices defining right and wrong that are usually transmitted from generation to generation, together with other kinds of customs and rules. Morality denotes a social institution, composed of a set of standards pervasively acknowledged by the members of the culture (p.4)

It is therefore likely that societies define morality in different ways. Several authors (Ikuenobe,1998; Verhoef & Michel, 1997) have attempted to provide frameworks for better understanding of African morality. While these frameworks were not primarily developed for the informed consent process, they serve to illuminate African moral/ethical principles, thus facilitating an understanding of the implications of the cross-cultural application of informed consent.

2.1.5 African morality

Verhoef and Michel (1997) assert that Western morality is fundamentally individualistic in nature. They define African morality as grounded in the context of communal life and primarily influenced by the community.

Morality in African cultures therefore tends to be communitarian. The needs, reality, and existence of the community take precedence over individual concerns (Menkiti, 1995 in Ikuenobe, 1998). Morality is also determined in terms of how much an individual is able to harmonize their interests to meet the interests of the community. Individual choice and freedom is therefore limited.

Elders are perceived as primary repositories of morality in African communities, and as capable of shaping moral principles. Because elders have had more experience, they are perceived as having wisdom (Ikuenobe, 1998). Young people are expected to honour their elders by obeying their commands, addressing them with titles of respect, accepting criticism, and following their advice (Verhoef & Michel, 1997).

If one fails to fulfill an obligation, such as refusing to take elders' recommendations into consideration, this is perceived as morally undesirable and tends to result in a weakening of the relationships that are essential for interdependence within the community. It is therefore unlikely that individuals will make decisions without influence from others. The notion of an individual who is not influenced by the community, but is an autonomous person, does not make sense in African societies (ibid).

Unlike Western moral processes that tend to emphasise the autonomy of an individual and his or her individual rights, and are thus de-ontological, African moral processes are ontological as they are primarily concerned with the social embeddedness of an individual and the maintenance of good relationships with others.

Whereas Western people tend to believe in absolute individual equality, the African perspective does not necessarily grant human beings with equality (Mbiti, 1975 in Verhoef &

Michel, 1997). Each individual is positioned uniquely within the community according to social variables such as age, gender, kinship, character, and wealth. African societies tend to place more emphasis on the interests of the community and one's duties towards it, than on individual rights. This has implications for how the principles of beneficence and justice might be applied.

Researchers might have to consider, for example, that the benefits of research participation are not primarily geared toward individual benefits, but accommodate the community, whilst ensuring that the individual is not negatively affected. Concerns with regard to what constitutes fairness might have to include the participant's community. Western and non-Western societies thus appear to have different conceptions of morality. Such differences have implications for the application of informed consent cross-culturally.

The next section explores the concept of culture in order to facilitate a discussion on the implications of the cross-cultural application of informed consent.

2.2 THE ROLE OF CULTURE

Ethical questions with regard to whether research participants are fully informed, willing, autonomous, face minimal risk to physical and mental health, and are treated with respect and dignity, become more difficult to answer when markedly divergent worldviews between researcher and participant are involved (Elliot, 1992 in Kempf, 1995, p.142).

2.2.1 Definitions of culture

Segall (1984) suggests that there is consensus that culture as a concept is unclear, that it has been frequently and variously defined, and that no single definition is embraced by anthropologists, in whose discipline the concept is central. Various definitions of culture have been provided and some are discussed below.

Culture as a set of human-made objective and subjective elements

Although there are many definitions of culture, Triandis (1994) suggests that there are agreed upon characteristics of culture, including that culture emerges in adaptive interactions

because humans communicate about social patterns and transmit to the next generation those elements which have been found to be useful. Culture also consists of shared language, time, and place. He therefore defines culture as:

> ...a set of human-made objective and subjective elements that in the past have increased the probability of survival and resulted in satisfactions for the participants in an ecological niche, and thus became shared among those who could communicate with each other because they had a common language and they live in the same time and place (p.11).

Culture as a set of values, attitudes, and beliefs

Matsumoto (1996) presents a somewhat different definition of culture from that of Triandis (1994). He contends that culture is often perceived as a single unitary concept that is true for all members of a group in exactly the same ways. He adds that it is commonly assumed that all people from a particular area are relatively homogenous with regard to some psychological traits, characteristics, or behaviour. Matsumoto believes that culture exists at the individual level, as much as it exists as a global, social construct. Individual differences in culture can therefore be observed among people in the degree to which they adopt and engage in the attitudes, values, beliefs and behaviours that, by consensus, constitute their culture. Norms are, for example, relevant in different degrees for different people.

Matsumoto therefore defines culture as "...the set of attitudes, values, beliefs, and behaviours shared by a group of people, but different for each individual, communicated from one generation to the next" (p.45). He clarifies that his definition of culture is not synonymous with race, because people of the same racial heritage may share the same socialization processes and be enculturated in similar ways. However, this does not mean that individuals from that racial heritage will similarly adopt the culture that is stereotypically associated with that racial group because culture entails learned behaviour. He feels that failure to recognise the existence of individual differences in constructs and concepts of culture has undoubtedly contributed to the formation of stereotypes which are generalizations about the culture of a group of people that are imposed on the individuals within that group.

Culture as a system of meanings

Culture is also seen as socially shared information coded in symbols (Mishra, 1997), and systems of meaning (Bruner, 1990; Rohner, 1984). Bruner (1990) asserts, for example, that all cultures have a "folk psychology" which is "...a system by which people organize their experience in, knowledge about, and transactions with the social world" (p.35). Folk psychology is therefore a set of more or less connected, more or less normative descriptions about what our own and other people's minds are like, what one expects a situated action to be, etc. Folk psychology is acquired early as people learn to use language and to conduct the interpersonal transactions required in communal life.

Bruner holds that the first premise of folk psychology is that people have beliefs and desires. People thus believe that the world is organized in certain ways, that people want certain things, and some things are perceived as more important than others. Beliefs are held about not only the present, but about the past and the future. There is also the belief that people's beliefs and desires become sufficiently coherent and well organized to warrant being called "commitments" or "ways of life" (ibid, p.39).

Rohner (1994) also provides a meaning-based definition of culture. He defines culture as "...the totality of equivalent and complementary learned meanings maintained by a human population, or by identifiable segments of a population, and transmitted from one generation to the next" (1984, p.119-120).

He clarifies, however, that the term "equivalent" refers to meanings that are approximately shared by most members of a particular society. He admits that two individuals would never hold precisely identical meanings and emphasizes that the term equivalence refers to approximate sharing. Although he asserts that a great part of cultural systems are generally transmitted across generations from parents to children, he maintains that some sets of meanings may be created and disappear within one generation. Rohner rejects the concept of cultural homogeneity and maintains that the culture of a group cannot be reliably inferred from the beliefs or behaviours of a single person. He recommends that definitions of culture must allow for the possibility of conflict, disagreement, innovation, creativity, and change.

There are numerous definitions of culture as has been suggested above. The cultural differences that exist between the Western and African contexts are the main focus of this study. The dimensions of cultural variability that have been described as applicable to these contexts are presented in the next section.

2.2.2 Dimensions of cultural variability: individualism and collectivism

The West, which includes countries like the United States of America and the United Kingdom, has been described as predominantly individualist in approach. Countries in Africa and the Far East have been described as predominantly collectivistic (Triandis, 1994). The differences between individualist and collectivist cultures will be discussed under various subheadings: child-rearing practices, construal of the self, decision-making, conceptions of intimate relationships and relationships with authority.

Child-rearing practices

Triandis (1994) suggests that individualist cultures tend to emphasize a child's autonomy, self-reliance, and independence. Collectivist cultures, on the other hand, tend to stress interdependence with in-group members, obedience, a sense of duty, and sacrifice for the in-group. Values such as conformity are encouraged in order to promote smooth ingroup relations (Schwartz, 1990). Individualist societies, on the other hand, tend to emphasize self-direction, achievement, stimulation, pleasure, and competition (ibid).

Construal of the self

Individualist cultures encourage an independent construal of the self whereby the self is largely perceived as a separate and distinct entity whose focus is on personal internal attributes such as individual abilities, personality traits, goals, and preferences (Matsumoto, 1996). A person from an individualist culture often gives priority to his or her own personal goals even when these goals are in conflict with the goals of important in-groups (Markus & Kitayama, 1994; Triandis, 1994).

Collectivist cultures tend to encourage an interdependent construal of the self. A person from a collectivist culture is more likely to sacrifice personal interests for collective interests, and

to give priority to sharing resources with group members. While the behaviour of a person from an individualist society is largely regulated by individual likes and dislikes, the behaviour of a person from a collectivist society is regulated by ingroup norms (Sihna & Verma, 1987 in Fijneman et al, 1996).

Conceptions of intimate relationships

Collectivist cultures are characterised by extended families, in which people have diffuse mutual obligations and expectations based largely on their enduring ascribed statuses (Schwartz, 1990). Individualist cultures, on the other hand, are characterised by nuclear families in which people develop specific obligations and expectations largely through negotiation in the process of achieving and modifying statuses (ibid). In-group fate, in-group achievement, and interdependence within the ingroup are emphasized by collectivist cultures, while individualist cultures encourage personal achievement, and independence from the ingroup (Matsumoto, 1996).

Decision-making

People from individualist cultures tend to decide for themselves what to do. They do not consult with ingroup members about matters that concern the individual. When faced with difficult problems they are more likely to decide what to do for themselves rather than follow the advice of others. People from collectivistic societies, on the other hand, tend to consult the ingroup about most issues, and turn to others for support and advice when in crisis (Triandis, 1994).

Relationships with authority figures

People from collectivist societies are often subordinate to ingroup authorities, possibly because they are encouraged to be obedient and conform in order to facilitate social harmony. Individualists rarely show subordination to ingroup authority figures, possibly because they are encouraged to be independent (Matsumoto, 1996).

The above-mentioned dichotomy is indicative of different conceptions of personhood within Western and non-Western settings. Various concerns have, however, been raised about the dimensions of cultural variability, and this is considered next.

2.2.3 A critique of the dimensions of cultural variability

Matsumoto (1994) suggests that any single culture can also have considerable variations among its members with regard to their need for independence or interdependence. Markus and Kitayama (1994) assert that cultural variability does not mean that collectivists do not have any awareness about their internal attributes such as personality traits, abilities, and attitudes. They maintain that internal attributes are relatively less salient in collectivists' consciousness and are thus unlikely to be the primary concerns in thought, emotion, and behaviour.

The independent view of self also does not argue for a permanent separation of self from the collective but tends to prescribe the terms of the relationship between the two. The positive aspects of collectivism are acknowledged, for example, people love one another, they show concern and sympathy and give to charity. Such prosocial behaviour is, however, intentional and voluntary, treated as an exception to be admired and rewarded and not as taken for granted as it is in collective societies (Markus & Kitayama, 1994, Matsumoto, 1994).

It has also been suggested that the dimensions of cultural variability seem to have the underlying assumption that cultures are constant and do not change over time. Various authors (Berry, 1995; Triandis, 1994) have alluded to cultural change and the implications thereof.

Schwartz (1990) suggests that the dimensions of cultural variability implicitly postulate that individualist and collectivist values form two coherent syndromes that are in polar opposition: different types of individualist values vary together consistently to form one set, and this set regularly opposes the types of collectivist values that also vary together consistently to form a second set. Schwartz states that although the hypothesis of polar opposites has received some support, it is often misleading. He asserts that the subtypes of

individualists' and collectivists' values sometimes do not vary together and are sometimes not opposed.

Individualism and collectivism have been discussed as dimensions of cultural variability. These dimensions of cultural variability, particularly the tendency to consult the collective and subordination to authority figure, is likely to impact on the informed consent process, particularly if the researchers are from individualist societies that emphasise the independence of the individual. There are indications, however, that there are considerable variations within a single culture, and cultures also do not remain static over time. Acculturation, a form of cultural change is discussed next.

2.3 ACCULTURATION

Triandis (1994) suggests that cultures are in constant flux and experiencing change. Such change can occur within a culture due to dynamic internal events (Berry, 1995). This internal process has been termed culture change. Change can also occur through contact with other cultures through a process called acculturation, which has been defined as:

> ...those phenomena which result when groups or individuals that have different cultures come into continuous first-hand contact, with subsequent changes in the original culture patterns of either or both groups... (Redfield, Linton, and Herskovits, 1936 in Berry, 1995, p.458)

This definition seems to suggest that the two cultures influence each other equally, but Berry argues that in practice one culture tends to dominate the other. He terms the former culture the "dominant group" (or "donor") culture; the other culture is termed the "acculturating group" (or "receptor") culture (1995, p.462).

Berry contends that westernization, modernization, industrialization, and Americanization are general precipitants of acculturation (1995). He suggests that the following are likely to facilitate acculturation: the purpose and length of contact between the cultural groups, the

population size of each group, the political and economic power that each group has, and each group's cultural qualities such as religion and education.

Acculturation may result in demographic changes in terms of rural or urban distribution, and the age or sex profile of the acculturating group (Berry, ibid). The economic system might also be altered, possibly with less dependence on the subsistence system. Acculturation might also mean that the acculturating group's independence is lost. There might be cultural influences: new languages, religions, modes of dress, schooling, transportation, housing, and forms of social organization and social relations, which might conflict with previous norms or partially displace, or merge them.

Societies that previously subscribed to collectivism might adopt individualistic tendencies, which might conflict with previous cultural beliefs (Georgas 1989, 1991). There might, however, be individual differences in the psychological characteristics that people bring to the acculturation process. Some domains of culture may become altered without comparable changes in other domains (Berry, 1995). The acculturation of values within African societies has been researched to a relatively limited degree.

Various definitions of culture have been presented. Individualism and collectivism, which were presented as dimensions of cultural variability, are indicative of different conceptions of personhood. It was suggested, however, that the dimensions seemed to overlook the change of culture over time. Cultural variability and acculturation are likely to influence the cross-cultural application of informed consent.

Concerns have been raised about the solicitation of individual informed consent from participants that subscribe to collectivism (Angell, 1992; Barry, 1992, Christakis, 1988; 1992; Ijsselmuiden & Faden, 1992). These concerns have contributed to the ongoing debate about whether ethical principles, such as informed consent and its particular emphasis on respect for the autonomy of the individual, are universal or determined by the cultural context in which they are applied. This debate is considered in the next section.

2.4. UNIVERSALITY VERSUS RELATIVITY DEBATE

It has been suggested that Western codes of ethics, such the Nuremberg Code and the Declaration of Helsinki made protection of the autonomy and personal dignity of research participants the focus of the informed consent process (Ijsselmuiden & Faden, 1992; Christakis, 1992; Gostin, 1995). Ijsselmuiden and Faden argue, however, that the Western emphasis on respect for autonomy with regard to ethical guidelines continues to be challenged. Verhoef and Michel (1997) state that there is an ongoing debate about whether ethical guidelines are universal or relative to the social context in which they are determined. The universal school of thought is presented first.

2.4.1 The universal school of thought

Verhoef and Michel indicate that this school contends that ethical principles are based on universal rationality; and that they should apply to all, across cultural lines, under all circumstances. This school has been largely informed by advocates of international human rights who have long claimed that some values, such as the protection of the freedom of individual choice are so fundamental to human existence that they should be universally applicable (Donoho, 1991). The universalist position thus presupposes some basic level of shared normative values and suggests that these human rights should be universally applicable because they are common to all people (ibid).

There has been widespread use of, for example, ethical principles developed in the West. Christakis (1992) suggests that this is possibly due to the fact that biomedical research is unique to the West, and non-Western medical systems lack an experimental tradition. The development of Western research ethics to contend with the Western tradition of human experimentation is probably the reason why Western research ethics have been universally adopted (ibid).

Proponents of the universalist position encourage the universal application of the principle of respect for autonomy. Questions have, however, been raised about the validity of soliciting individual informed consent, which is primarily based on individualism, from people in collectivist societies that emphasise the social embeddedness of the individual rather than his

or her autonomy from the collective (Barry, 1992.; Christakis, 1988; 1992; Gostin, 1995). Suggestions have been made that this might be perceived as tantamount to "ethical imperialism" (Angell, 1992), which has been described as the imposition of Western values on non-Western contexts (Benatar, 1992).

Kleinman (1990 in Christakis, 1992, p.1080) suggests that cross-cultural research is likely to result in medico-cultural conflict":

> Clinical investigations in developing countries must be understood as taking place within the particular contexts of practical, everyday beliefs, values, and power relationships that constitute local cultural systems and (must be understood) as creating potential conflicts between these non-Western systems and the Western cultural conceptions and norms that are usually an unrecognized part of clinical research projects and the expectations and behaviours of clinical researchers...Clinical investigations (result in problems) because of different and often conflicting cultural constructions of what clinical research is, how it is conducted, and what is to be gained from it.

Kleinman recommends that these cultural differences be taken into consideration in order to prevent cultural conflict. The relativist position, which challenges the underlying assumptions of the universalist position is considered next

2.4.2 The relativist school of thought

Some scholars seriously challenge the claims of universality of ethical principles, and argue that all moral values, including human rights, are relative to the cultural context in which they arise (Christakis, 1992; Donoho, 1991). This relativist perspective asserts that morals are the rules that regulate a given society and that each ethical code, and what is considered moral behaviour, varies from society to society (Verhoef & Michel, 1997). The latter argument has been widely supported by scholars from developing countries who have objected to current universal standards on the basis that they are insensitive to or incompatible with various cultural, political, and social conditions (Christakis, 1992).

Christakis also suggests that the relativist debate is largely informed by anthropologists' assertion that divergent cultural and political traditions result in equally divergent social values and diverse approaches toward morality and law. Cultural relativists object to a perceived overemphasis on the individual, in contrast to, for example, collective rights. They are therefore likely to challenge the solicitation of individual informed consent, and possibly encourage a multi-party consent process (that includes leaders and family) for societies that subscribe to collectivism.

Ethical guidelines that emphasise the autonomy of the individual are likely to be perceived as culturally biased, because of their failure to reflect the varied cultural, political and social heritages of the non-Western world. Such scholars advocate the development of contextual theoretical frameworks which are culturally grounded and representative of a people's history and psyche.

Donoho (1991) asserts that relativism involves a combination of three related propositions: the first proposition is that an observable divergence exists among societies as a result of their differing cultural, political, and social traditions. The second proposition asserts that the divergent moral judgements outlined in the first proposition have no meaning or validity outside their particular context: "what is right or good for one individual or society is not right or good for another, even if the situations involved are similar" (ibid, p.351). The last proposition asserts that no objectively justifiable moral standards or judgements exist outside particular cultural contexts.

Concerns have been raised about the appropriateness of the relativist approach (Angell, 1992; Ijsselmuiden & Faden, 1986). Angell suggests that the relativist approach seems to imply that ethical standards are matters of custom, like table manners, and that their content is irrelevant provided they are indigenous. She adds that the relativist approach presupposes that members of a particular community share its dominant values, and this might inadvertently curtail individual freedom.

Suggestions have been made that the call for relativism might encourage "double standards" whereby Western researchers working in African contexts would adopt lower standards that would be unacceptable in the West (Benatar, 1992; Ijsselmuiden & Faden, 1992; Olivier, 1995). This might involve foregoing the often numerous requirements for protecting human subjects under the pretext of cultural relativism; particularly because the ethical guidelines tend to be less rigid in developing countries (Adityanjee, 1986).

Goldberger and Veroff (1995) add that critics of relativism suggest that relativism implies giving up science altogether, and threatens to replace it with chaos within which no theory or belief has any greater truth or claim than any other. It has also been suggested that humans are biologically the same. This guarantees a sameness of survival needs and the possibilities of responding in similar ways regardless of culture.

Various authors clarify that they are not suggesting that Western researchers should not make appropriate accommodations for local customs (Angell, 1992; Ijsselmuiden & Faden, 1992; Olivier, 1995). They state that it may be necessary to obtain permission from community leaders to enroll members of the community or from a husband to enroll his wife. They stress, however, that such consultation should not be a substitute for informed consent from the participants themselves or override a prospective participant's refusal to participate.

Angell calls for a core of human rights that would be "...honoured universally, despite local variations in their superficial aspects" (1992, p.1082). She maintains that the force of local custom or law cannot be allowed to justify abuses of certain fundamental rights, such as the right of self-determination, on which the concept of informed consent is based. Angell asserts that the fundamental human rights that she calls for should not be compromised but be protected by an irreducible set of ethical standards (ibid).

Goldberger and Veroff (1995) assert that the debate between universalists and relativists sometimes leaves out consideration of power relationships that are usually involved in who is studying whom and by what method, for what purpose, and with what already embedded assumptions about the nature of truth. The debate continues, however, to be an area of great

controversy within the realm of cross-cultural research (Verhoef & Michel, 1997). The current application of informed consent is considered in the next session, with particular focus on the challenges likely to be encountered, and the implications of the universalist and relativist debate presented above.

2.5 THE CURRENT APPLICATION OF INFORMED CONSENT

Although the necessity of informed consent was firmly established almost four decades ago, challenges continue to surround its application.

2.5.1 Challenges facing the components of informed consent

Although there is consensus that informed consent should be a necessary feature of medical and research settings, strong reactions continue to surround the concept. The challenges facing various components of informed consent are discussed below.

Information

Although most informed consent protocols tend to be fairly similar in outlining the specific items for disclosure, it remains unclear how much information should be provided (Belmont Report, 1979). Strull, Lo, and Charles' study (1984) suggests that participants generally receive less information than they would prefer to receive about proposed research interventions. Participants admitted, however, that they played a relatively passive role in actual decision making, thus leaving the decision-making to the researcher.

Lesko, Dermatis, Penman, and Holland's study (1989) suggests that this passivity may be due to participants' perceptions that the researcher did not want them to make their own decisions. Researchers, on the other hand, felt that most participants withheld doubts and concerns and seemed to prefer that the researchers make the decisions, and thus do not actively encourage participants' participation in the decision-making process.

Understanding

Meisel and Roth (1983) state that there is a need to describe, define, and operationalize understanding. Most researchers tend to equate understanding with recall of transmitted

information which is indicative of "...a fundamental misunderstanding of informed consent" (ibid, p.288), since understanding is not limited to short-term memory.

The view that lay people cannot give informed consent because they cannot understand complex medical information has been expressed (Meisel & Kuczewski, 1996). Silva and Sorrell (1984) mention that research participants often do not understand major portions of the procedures to which they have consented.

Contradictory results have been found in relation to the effects of total disclosure on understanding. Simes, Tattersall, Coates, Raghavan, Solomon, and Smart (1986) conducted a study whose results indicate that total disclosure facilitates better understanding of the treatment and side effects, but results in reluctance to consent to randomised treatment, and increased anxiety. Quaid, Faden, Vining and Freeman's study (1990), on the other hand, provides no evidence of the hypothesized negative effects of total disclosure, such as anxiety, treatment refusals, and reduced compliance.

Competency

Although infants and young children, mentally disabled patients, the terminally ill, and the comatose are commonly identified as with limited competency, there is, however, little clarity for what incompetency or lack of capacity involves beyond the groups outlined above (Belmont Report, 1979).

Voluntariness

Meisel and Roth (1983) state that there is a dearth of literature on voluntariness, possibly due to the challenges of investigating this component. The principle of voluntariness is susceptible to undue influence, through, for example the offer of an excessive, unwarranted, inappropriate or improper reward in order to obtain compliance (Belmont Report, 1979).

Consent

Meisel and Kuczewski (1996) assert that the most pervasive myth about informed consent is that informed consent has been achieved when a participant signs an informed consent form.

Although informed consent forms enable participants to read about the study, the fact that a participant has read and signed the informed consent form is no guarantee that the participant has understood the information and thus given informed consent. Valid informed consent can only be achieved when there is some certainty that the participant has understood the information provided (ibid).

Adityanjee (1986) suggests that informed consent has complications wherever it is conducted, but becomes even more challenging when conducted cross-culturally. Gostin (1995) asserts that the doctrine of informed consent is grounded in the ethical principle of respect for persons that regards individuals as autonomous agents, who are "capable of deliberation about personal goals and of acting under the direction of such deliberation" (Belmont Report, 1979, p.3).

The Western ethical codifications that have influenced the informed consent process world-wide appear to regard informed consent as a universal expression of respect for the autonomy of individuals. There is emphasis on the need for full disclosure to enable individuals to make informed and voluntary decisions. The right to autonomy or self-determination is thus perceived as a morally necessary method for demonstrating genuine respect for human integrity (Gostin, 1995).

There are indications, however, that individual/first-person informed consent may have to be reconsidered when applied in collectivistic societies. The various concerns that have been raised about individual or first-person informed consent are considered next.

2.5.2 A critique of first-person informed consent

It has been suggested that first-person informed consent is inappropriate for collectivistic cultures (Adityanjee, 1986; Barry, 1992; Christakis, 1988; 1992; Gostin, 1995). The reasons provided for the inappropriateness are explored below.

Differences in conceptions of personhood

Christakis (1992) suggests that the informed consent process involves the solicitation of individual informed consent after the transmission of information about the research study. The application of the principle of respect for persons is, however, complicated by cross-cultural variations in the definition of personhood. Western societies have been described as emphasising the autonomy, and thus the self-determination and privacy of the individual (Triandis, 1994). Such societies are likely to encourage an informed consent process that is individual-oriented, whereby the decision about whether or not to participate is perceived as an individual's own responsibility.

Gostin (1995) poses a challenging question: "...is the kind of rugged individualism inherent in informed consent truly respectful of people in all cultures?" (p.844). Some authors have suggested that the universalistic application of individual informed consent is not respectful of everyone (Barry, 1992; Christakis, 1988; 1992; Gostin, 1995) because, for some collectivistic cultures, the very concept of respect for persons as individuals is at "...variance with more relational definitions of the person found in other societies, especially in Africa, which stress the embeddedness of the individual within society and define a person by his or her relations to others" (Christakis, 1988, p.35). Barry suggests, for example, that personhood is defined by one's tribal village, or social group and not primarily by the individual within collectivist African societies (1992).

Christakis (1992) suggests that in societies that stress a relational concept of personhood, the notion of people as individuals is undermined and individual consent is therefore likely to be perceived as nonessential. Christakis recommends that the consent process shift from the individual to the family or community if the notion of people as individuals is not dominant.

Various authors have recommended the involvement of families when working with cultures that emphasise relatedness (Adityanjee, 1986; Chirstakis, 1988; 1992; Gostin, 1995). Adityanjee (1986) recommends that prospective participants be given time to consider whether they would like to give their consent to participate or not. He asserts that this might enable the participants to consult their relatives and friends in order to make a decision based

on collective consideration. This process might involve informing the prospective participant about the research intervention, and possibly soliciting informal consent. The intended procedures of the intervention would later be explained again, after family consultation, with the aim of procuring formal consent (Adityanjee, 1986).

Gostin (1995) suggests that researchers' insistence on autonomous decision-making may counter family-centred values. He adds that the concept of uncoerced choices that is frequently highlighted in informed consent protocols, may undermine cultural norms that emphasize, for example, obedience to the wishes of spouses or family elders.

The formal aspects of individual informed consent, such as full disclosure, isolated individual decision making, and written consent forms may serve to advance individual autonomy and human dignity for Western research participants, but alienate and dehumanize people that uphold relatedness (ibid). Gostin believes that obtaining informed consent in a manner that is consistent with a person□s language, custom, and culture is indicative of respect for human dignity.

The nature of informed consent

Christakis (1988) asserts that the type of informed consent practised in the West, which entails the signing of an informed consent document with scientific terminology, is inappropriate for illiterate or semi-literate people. The signing or even thumb-printing of a consent form may be perceived as highly suspect in certain societies, coupled with a physician or researcher's "excessive" explanation of the purpose of research, which may be perceived as indicative of some hidden, detrimental purpose.

Limited understanding of research

Christakis (1988) asserts that African research participants generally have minimal understanding, if at all, of all the aspects of research participation. This is possibly because the concept of experimental evaluation of therapy is alien to, and inconsistent with, cultural precepts of some developing countries (CIOMS & WHO, 1982). An accurate understanding of the concept of randomization may prove difficult to convey in some cultural settings.

Although terms such as "randomized', "double-bind', "control group", and "informed consent" are understood by researchers, they are not easily understood by non-researchers, even if they are first language speakers of English. The situation is exacerbated when research is conducted on largely illiterate people who have very little, if any, command of the English language (Valdiserri et al, 1988).

Adityanjee (1986) contends, however, that the concern that semi-literate or illiterate participants may not be able to comprehend technical information presented during the informed consent process is more theoretical than real. Barry (1992) acknowledges that illiteracy might present difficulties during the informed consent process, but adds that this should never be confused with lack of intelligence on the part of prospective participants.

It has been suggested that community leaders may play an important role during the informed consent process:

> Where individual members of a community do not have the necessary awareness of the implications of participation in an experiment to give adequately informed consent directly to the investigation, it is desirable that the decision whether or not to participate should be elicited through the intermediary of a trusted community leader (CIOMS & WHO, 1982, p.1).

It is recommended that the leader make it clear to subordinates that participation is entirely voluntary and that refusal to participate and withdrawal from participation will not have negative repercussions (ibid). Individual informed consent is therefore not abandoned, but supplemented.

There might be variations in terms of who is acknowledged as a properly authorized leader, but Christakis (1988) recommends that the Western researcher should respect the alternative of proxy consent by a leader, because although it might be unsatisfactory by Western standards, it may be ethically acceptable in the non-Western society that is being researched.

He adds (1992) that such procedures might be the only alternative to informed consent in cross-cultural research. He cautions, however, that research participants' respect for local authorities should not be abused by Western researchers to the detriment of the prospective participants. Adityanjee recommends that the representative or leader should make it clear to his or her subordinates that participation is entirely voluntary and that refusal to participate and withdrawal for participation will not have negative repercussions.

Both Adityanjee (1986) and Christakis (1988; 1992) admit, however, that proxy consent is not without its challenges. There is a possibility that the individual that refuses to participate or withdraws during the research investigation may experience social pressure for differing with the opinion of the community leader. The leader may be susceptible to inducements or bribes, thus defeating the purpose of voluntary informed consent. It has been suggested that there must be certainty that the community leader is acting in good faith, on behalf of his or her constituents, and with their approval; but it remains unclear how this might be achieved (Adityanjee, 1986; Christakis, 1992).

Christakis (1988) states that researchers may have to ask a man to give consent for his wife to participate in research in some societies.

The importance of the interests of society

The Declaration of Helsinki states, as mentioned above, that "...concern for the interests of the subject must always prevail over the interest of science and society" (1964, p.3). Questions have, however, been raised about the cross-cultural application of this principle.

The relational definition of personhood that is commonly found in non-Western societies may, according to Western ethical standards, unduly favour the interests of the society at large, at risk to the individual (Christakis, 1992). Anticipated benefits for one's society might be perceived as more important than anticipated risks to the individual in some contexts. This would not be regarded as necessarily compromising the rights of research participants. A research participant from a society that holds relational views of personhood might have difficulties understanding how individual interests of participants conflict with the interests of

the society, unless that society was not his or her own, because individual and societal interests are perceived as congruent (ibid).

A critique of first-person informed consent has been presented. It has been stated that for societies that place more emphasis on the social embeddedness of an individual than on his or her autonomy, first-person or individual informed consent may not be the most appropriate approach for the reasons presented above. The researchers may have to involve both family members and community leaders of the individual participants in the informed consent process. The perspective that supports the universal application of respect for the autonomy of the individual is presented in the following section.

2.5.3 Support for first-person informed consent

Ijsselmuiden and Faden (1992) assert that first-person consent is indicative of important and basic moral values that are universally applicable, regardless of variations in cultural practice. They indicate that the appropriateness of first-person informed consent has been questioned on three grounds: firstly, it has been described as culturally inappropriate; secondly, that prospective participants have questionable competence to give informed consent or that there are insurmountable communication problems; and thirdly, that the need for immediate research findings makes informed consent requirements unreasonable. A discussion of these concerns follows:

Cultural inappropriateness of first-person informed consent

Ijsselmuiden and Faden indicate that anthropological literature on Africa asserts that an African person is embedded in his or her social context. An African person typically perceives himself or herself as an extension of the family rather than as an individual person in his or her own right. Anthropological African literature states that authority is located in the leader of a village or tribe and in the head of the household, who is often a man.

Ijsselmuiden and Faden challenge the call for the waiving of first-person informed consent on the basis of cultural inappropriateness. They argue that although African anthropological literature gives the impression that there is only one culture on the African continent; there

are numerous cultures in Africa which have not been static. Forces such as urbanization, education, industrialization, prolonged civil warfare, and the HIV/AIDS pandemic have resulted in changes for African traditional life. The AIDS pandemic itself has also had an impact on African life.

Ijsselmuiden and Faden question the recommendation that in addition to, or even instead of, first-person informed consent, researchers should, if there are indications that people do not have the necessary awareness of the implications of participation to give informed consent, solicit consent through the intermediary of a trusted community leader (CIOMS & WHO, 1982). They believe that there are few such leaders left as a result of urbanization and development. Difficulties identifying who they are and in assessing whether they are trusted or not might arise.

There would also be no certainty that community leaders speak for all community members, as there are immigrants and the landless who may not be subjects of that particular leader. Traditional leaders have also been wiped out in some African countries and replaced by party officials as a result of political changes. Although Ijsselmuiden and Faden admit that there are some trusted village leaders left, the concerns raised above highlight the difficulty of identifying them.

Ijsselmuiden and Faden also challenge the recommendations that proxy consent be given by heads of households on behalf of women. They contend that the migrant labour system has resulted in most male heads residing in urban areas for the greater part of the year. Women's educational status and the number of households that are headed by women are increasing, thus raising concerns about the justification for soliciting male consent for competent female adults. Ijsselmuiden and Faden clarify that they are not suggesting that the custom of informing village leaders and heads of households be omitted. Instead they are challenging the solicitation of leaders' and husbands' consent instead of that of individual participants.

Competency and communication problems

Ijsselmuiden and Faden allege that the term "incompetence" (p.831) is being used confusingly in the cross-cultural literature on informed consent to refer to a state of mental incompetence or difficulties in communication and comprehension as a result of differences in language, poor education and nonscientific conceptions of health and illness. They add that there have been suggestions that researchers should adapt the information that they generally use in Western settings to accommodate local conceptions of disease and health.

Ijsselmuiden and Faden suggest that concerns about comprehension are informed by the perception that obtaining valid consent from participants in developing countries is time-consuming and difficult, if not impossible. They allege that this is made clear in the CIOMS guidelines which, they claim, give the impression that participants from developing countries demonstrate a lack of competency that is analogous to that of children and the mentally ill. They state that this presumption is false if not downright insulting.

The authors question the belief that because Western investigators and their research participants do not share a common understanding of health and illness or of the scientific enterprise, valid informed consent cannot be obtained. They contend that Western literature on doctor-patient and scientist-participant relations is suggestive of differences in language and culture, and a lack of shared understanding of health and disease that have contributed to miscommunication. They note, however, that no one has argued that different consent practices should be implemented on the basis of different cultures and social classes.

Ijsselmuiden and Faden (1992) allege that concerns about cultural and communication gaps tend to overstate the requirements necessary for valid informed consent to be obtained in cross-cultural settings. They acknowledge that research requirements for cross-cultural research may be more demanding than in the West, but state that the challenges that exist do not make the solicitation of valid informed consent impossible.

Research urgency in the developing world

Ijsselmuiden and Faden state that the third reason presented for waiving first-person informed consent is that the need for research results is so paramount that the time required to obtain informed consent cannot be justified. They contend, however, that this sense of urgency in clinical trials is often unwarranted as the conduct of past research in Africa suggests that rapid responses to positive research findings are unlikely in the developing countries. They allege that past research has been conducted without any commitment by the researchers that positive results would enable Africa to benefit from the studies by means of availability or reduced costs of treatment.

Ijsselmuiden and Faden (1992) argue that although the ethical guidelines provided in the CIOMS document were intended to facilitate the formulation of ethical principles for cross-cultural research, they are however vague and thus allow for any method of obtaining consent.

Support for first-person informed consent is informed by the desire for universal application of the principle of respect for an individual' autonomy. It has been suggested that cultures are fluid and this results in social changes. Ijsselmuiden and Faden express no support for the idea that first-person informed consent may not be appropriate for some settings.

The main differences between the two perspectives are that the universalists believe that respect for the autonomy of the individual is a universal principle that should be applied everywhere. The relativists, on the other hand, suggest that ethical principles are relative to particular contexts.

There is general consensus, however, that cultural differences exist between Western and non-Western contexts. Both universalists and relativists believe that such cultural differences must be respected, for example, by informing leaders about research conducted in their areas of jurisdiction. They differ on the degree of importance they attach to the role of the individual within his or her society. While the universalists stress the importance of individual consent above all, the relativists suggest that researchers the involvement of

leaders and families in the consent process is necessary for societies that encourage relatedness. Proxy consent of the leaders and husbands of the participants may have to obtained if there are indications that participants' understanding is limited. Relativists also suggest that proxy consent may sometimes be the only alternative in some societies.

2.6 CONCLUSION

It is clear from the contradictory ideas presented throughout the literature review that there is a need for more research in the field of cultural conceptions of informed consent. South African research is very limited, and this is unfortunate since South Africa is likely to be an ideal context for research, because of its multi-cultural nature.

As indicated at the beginning of the literature review, there are few definitions of informed consent that cover all the components of informed consent. It was also highlighted that the informed consent process presents with challenges wherever it is conducted. The problems are, however, exacerbated when informed consent is solicited in a cross-cultural setting, particularly as a result of the individualistic and collectivistic dimensions of cultural variability that were presented. Suggestions were made, however, that cultures have not remained static over time, and it is possible that cultures have changed as a result of inter-cultural contact. There is presently limited information on culture change, particularly in South Africa, and this is an area that might benefit from further research.

Informed consent processes that are primarily informed by Western conceptions of persoonhood continue to be used cross-culturally in a formalistic way, despite the observed cross-cultural differences. It was indicated in the literature review that the legal and moral foundations on which informed consent is based are likely to prove challenging when applied cross-culturally, as they are largely informed by Western principles of conduct.

The upsurge of research by Western researchers in the non-Western countries has resulted in an ongoing debate between universalists who suggest that ethical guidelines primarily developed in the West apply to all people cross-culturally since they are based on universal moral principles, and the relativists who argue that morality is determined by the context and

therefore varies from society to society. Further research on the cross-cultural application of ethical principles seems warranted, particularly with regard to informed consent.

2.7 JUSTIFICATION FOR THE STUDY

A decision was made to research the Hlabisa community in Northern KwaZulu-Natal for various reasons. This community has been identified as a HIVNET site for vaccine testing, and informed consent has been identified as a relevant concern for the site preparation. It was felt that the Hlabisa community, as a largely traditional community, would be an appropriate setting for exploring the cultural conceptions of research and informed consent. Hlabisa has also been extensively researched and it was thought that community members perceptions about research would prove informative.

It became clear, however, that the community had been exposed to various situations that had resulted in changes in the cultural beliefs of the area. Like most of Africa, the Hlabisa community has been exposed to Western civilisation. Western education, religion, mode of dress, medicine, and much more, bear testimony to the influence of the Western culture on the community. These changes, and many others, have resulted in changes in the cultural beliefs and traditional life of the community.

It was therefore felt that the Hlabisa community would also be informative in terms of cultural changes within the African culture. The implications of this for research and informed consent would be explored. The aims and objectives of the study are discussed next.

2.8 AIMS

The field of culture and informed consent presents with contradictory findings, as indicated in the literature review. As a result of this, and the limited local literature written on the area, the aims of this study are largely exploratory. They are also influenced by preparation for the HIVNET project.

The aims of the study are:

- To explore the cultural understanding of research and the informed consent process in Hlabisa
- To facilitate cultural sensitivity during the informed consent process of the HIVNET research project
- To facilitate the community consultation process in preparation of the HIVNET research project

2.9 OBJECTIVES

The objectives of the study are to interview key informants from Hlabisa in order to explore:

- understandings of research and how they have been influenced by past research experiences;
- understandings of the informed consent process and components such as information disclosure, understanding, consultation, motivation, voluntariness, and actual consent;
- how key informants views can be understood in terms of individualistic and collectivistic approaches to the informed consent process;
- possible cultural changes with regard to individualistic and collectivistic orientations.

3. METHOD

The methodological procedures of the study are presented in this chapter. The research participants are introduced first. Justification for the qualitative research paradigm and the narrative method are outlined next. The interview guide used for the semi-structured interviews is then presented. The data collection procedures are outlined, including the challenges encountered during this process. This is followed by a discussion on the data analysis method. The ethical issues of the study and the limitations of the method are considered last.

3.1 RESEARCH PARTICIPANTS

Twenty-three key informants were interviewed; thirteen were women, and ten were men. They are all Zulu-speaking Africans from the Hlabisa community. Their ages range between twenty-two and sixty-six years. They occupied different professions: three are Hospital employees, four are teachers, while two occupied religious positions. The business sector, the protection services, the welfare department, and the magistrate's court were each represented by one person. The women's empowerment groups were represented by four participants. There were four traditional healers and two traditional leaders.

3.3.1 Maximum variation sampling

Maximum variation sampling, which is a type of purposive sampling was used (Patton, 1990). A decision was made to approach only people who were perceived as occupying influential positions within the Hlabisa community because it was thought that the varied leadership positions that informants occupied enabled them to maintain direct contact with most Hlabisa people. They would thus be informed about the general ideas, beliefs, opinions, and norms of the community members or at least be able to render a portrayal of these ideas, beliefs, opinions, and norms. The informants were also chosen to reflect differences as influenced by education, profession, religion, tradition, age and gender.

Maximum variation sampling thus facilitated a process whereby the informants, who occupied different influential positions would be invited to share their perceptions about

research and informed consent. This type of sampling facilitated an exploration of individual uniqueness with regard to cultural notions of research and informed consent, whilst yielding important shared patterns. The researcher did not seek to make generalizations, but sought information that elucidated both significant variations and common patterns across participants.

The limitations of the sampling procedure

Attempts were made to ensure that the sample was representative of people in leadership positions in Hlabisa. It became difficult, however, to obtain nearly the same number of leaders from each sector, as the levels of their availability varied. Some institutions also had more employees than others and the numbers of informants selected were influenced by this factor. Some influential institutions, such as the Department of Agriculture, were not represented. It can thus be argued that some sectors were less represented then others, and this might have resulted in information bias.

3.2 JUSTIFICATION FOR THE QUALITATIVE RESEARCH PARADIGM

A decision was made to conduct the study within the qualitative research paradigm and the reasons for this are provided below:

Research into real life

Qualitative research appeared to be the most appropriate paradigm for the present study, as it is directly concerned with experience as it is lived or felt. The focus of qualitative research is on the depth and essentially the quality of people's experiences, and not on the number of people who respond in a particular way (Stake, 1990 in Miles & Huberman, 1994). "Qualitative research, then, has the aim of understanding experience as nearly as possible as its participants live it" (Sherman & Webb, 1988 in Miles & Huberman, 1994, p.14).

Research into meaning

Because qualitative data places its emphasis on people's lived experience, it is essential for identifying the meanings that people place on the events, processes, and structures of their lives such as their "perceptions, assumptions, prejudgements, presuppositions" (Miles &

Huberman, 1994, p.10). Qualitative research also facilitates an understanding of latent, underlying, or non-obvious issues.

Qualitative research seemed to be the paradigm that would enable the researcher to explore the meanings attributed to research and informed consent. Qualitative research also gives the intricate details about phenomena that are difficult to convey through quantitative methods (Strauss & Corbin, 1990).

Fish (1990, in Tappan and Brown, 1992) argues, however, that an interpreter's personal, relational, and social context, as well as specific ethical and political values shape and influence his or her interpretation of a text. It might then prove difficult for researchers to distance themselves from research interviews as they bring their values, biases, assumptions, and commitments to the research situation.

Dickson (1995) also cautions qualitative researchers against imposing their own meaning of an event or experience on the insights and perceptions of the research participants that they seek to understand. This is likely to be exacerbated if the researcher and the participants belong to societies that differ in terms of cultural, economic, and political contexts. It can be argued, however, that researchers are also likely to impose their own meanings when few "apparent" differences between the researcher and the community exist.

Dickson adds that qualitative research requires that the researcher be a flexible instrument by becoming personally and subjectively involved with the research participant while constantly monitoring his or her own behaviour to minimise bias and subjectivity. She adds that these two simultaneous roles make qualitative research a challenging task.

Narrative methodology, a subsection of the qualitative research paradigm, is presented next.

3.3 THEORETICAL JUSTIFICATION FOR NARRATIVE METHODOLOGY

Mishler (1986) argues that the interview is a central research method in the social sciences as it enables the interviewer to enquire about people's attitudes, beliefs, and values. The semi-

structured interviews described below were designed to elicit narratives about cultural conceptions of research and informed consent within the cultural context of Hlabisa. Theoretical justification for the use of the narrative approach is considered below.

A general assumption of the narrative approach is that telling stories is one of the significant ways in which individuals construct and express meaning. Human beings are interpreting beings who are active in the interpretation of their experiences as they live their lives (White, 1995). A narrative or story is therefore a mode through which individuals express their understanding of events and experiences (Mishler, 1986). Stories provide the frame of intelligibility that enables people to interpret their experiences, thus making the distribution of meaning possible (White, 1995). The meanings derived through this process of interpretation are not neutral in their effects on people's lives, but have an impact on what people do, and the steps they take in life.

White asserts that the narratives that people tell determine which aspects of their lived experience get expressed. People's narratives have ambiguities, contradictions, and contingencies that stress their meaning-making resources. People continuously try to resolve these contradictions and ambiguities in order to make sense out of significant experiences that cannot be readily interpreted. During this process, some of the sub-narratives of people's lives are elevated and invoked in order to facilitate understanding (ibid).

White adds that people's thoughts, values, relationships with others are largely determined by conceptions of personhood. The stories that people tell are therefore determined by how people perceive their personhood. If a person has been socialised to be an autonomous agent within an individualistic society, this is likely to determine the type of stories that he or she tells. White contends that stories of what it means to be a person of moral worth are culture-specific, and are likely to vary from culture to culture.

The narrative approach was therefore perceived as likely to give the researcher insight into the attitudes, values, beliefs, and behaviours shared by the Hlabisa people, as well as how these were also different among the individuals interviewed. It was also thought that the

narrative approach would facilitate insight into how key informants understood research in general, as this would have an impact on their responses to present and future research. The narratives that informants told were also perceived as likely to enable the researcher to explore the meanings that people attached to research and informed consent.

A decision was made that the narrative approach would be used to explore shared cultural models, particularly in relation to the suggestion that stories told are largely determined by conception of personhood. There was also an interest in how each individual that was interviewed experienced, transformed, and participated in the creation of shared knowledge. It was thought the narratives would provide an exploration of how people's cultural beliefs had changed due to, for example, Westernization, personal preferences, economic changes such as the increase in migration, etc.

A semi-structured interview guide (See Appendix A) was formulated with the intention of facilitating narrative disclosure of the conceptions of research and informed consent. The pilot study, that was conducted in order to assess the feasibility of the study, is discussed first.

3.4 THE PILOT STUDY

The pilot study was conducted in order to assess how the interview schedule for the main study could be modified for better results. The researcher wanted to test whether the questions were accessible and appropriate. It was thought that the pilot study would enable the researcher to gain insight into the range of responses that could be expected from the study. The researcher wanted to establish how some ideas might be explored and how that could be done, for example, which probes to use in order to obtain the depth of information required. It was hoped that the pilot study would provide a forum for assessing whether other important issues had been omitted or not.

Five people who occupied leadership positions within the hospital, business, religion, education, and non-governmental sectors were interviewed in order to test the feasibility of the study. They were interviewed because they shared similar characteristics with the informants that participated in the main study. The five participants were interviewed broadly

about research in Hlabisa, informed consent and culture, and people's motivations for participating in research.

The three main questions of the Interview Schedule (See Appendix A) that broadly cover perceptions of research, informed consent and projected motivations for research participation were translated into Zulu. A colleague that works in the Zulu Department of the University of Natal was asked to check whether the translated version retained the meaning of the original questions, and she felt that the questions did retain the meaning.

The participants were asked the main questions and given time for spontaneous responses. The researcher then asked various probing questions in order to obtain the desired level of understanding. The pilot study proved informative with regard to preparation for the main study. All the participants described the questions as accessible and appropriate. Although some participants mentioned that there was general unhappiness about the manner in which past research had been conducted, some were rather reluctant to refer to the topic when they responded to the question: what do you think research is? Some even enquired about what would be done with the information they gave to the present researcher.

It was then decided that it might prove informative to use an interactive manner of questioning and indicate to informants of the main study that the researcher had already heard stories about unhappiness with past research. It was hoped that this would enable the informants to relax and communicate about past experiences.

Participants sometimes gave very brief information in response to the second question on informed consent. This was indicative of the need for more probes that would guide the informants of the main study about the depth of information required. Participants did not indicate that some ideas had been omitted. The pilot study proved informative with regard to what could be expected from the main study. The procedures followed in preparation for the main study are presented below.

3.5. THE RESEARCH PROCESS

3.5.1 Community Entry

The researcher, in her capacity as a researcher/counsellor for the HIVNET project, became part of the intensive community entry process that had already been initiated by two Community Liaison Officers who are employed by the Medical Research Council. A large number of sectors that were described by the Liaison Officers as influential in the Hlabisa community were consulted: health, education, traditional leaders, traditional healers, the church, business, protection services, welfare, and women's empowerment.

Introduction

The respective sectors were approached so that the researcher could be introduced. The Tribal Authority Office was approached first as an indication of respect for the cultural norms of the area, such as the importance of informing traditional leaders about any project to be conducted in their area of jurisdiction. Although traditional leaders' permission for the broader HIVNET project had already been obtained, it was felt that it might prove beneficial to obtain permission for this particular study as well.

The Community Liaison Officers routinely mentioned that the researcher comes from Pietermaritzburg and that she works for the Medical Research Council. It was mentioned that the researcher had come to Hlabisa to conduct research into key people's perceptions about research and informed consent as part of the community consultation process of HIVNET project. An attempt was made to disclose all relevant information to ensure that people did not feel that information had been deliberately withheld from them, thus affecting the researcher's relationship with them.

It was explained, for example, that the researcher felt that it would be necessary to interview key people as they are in constant contact with Hlabisa people, and would therefore be better able to comment on people's beliefs, experiences, and preferences. The objective was to gain insight into people's cultural understanding of research and informed consent in order to

design appropriate procedures for the forthcoming HIVNET project. The researcher was often asked to re-introduce herself and restate her intentions.

Appointments

Subsequent visits were then made to the respective institutions with the intention of making appointments with the key informants. Decisions regarding who would be interviewed as representatives of their institutions were consultative, and were made by the people within a particular sector, with the research team, on the basis of availability, and experience. The researcher then made appointments to meet with the key informants. Appointment times were determined by each participant's availability. This process proved very challenging as the key informants had numerous commitments.

The researcher drove to the informants' work places because some of them did not have their own transport and it was thought that public transport was unpredictable and could interfere with appointment times. The interviews were conducted in offices with minimal disruptions within the respective institutions. If the informant indicated that organizing a quiet office might be difficult, she or he was fetched and interviewed in the researcher's office.

In general, informants expressed interest in a project that sought their opinions about Hlabisa people's conceptions of research and informed consent. The various challenges encountered during the process outlined above are described next.

Challenges encountered

A number of challenges were encountered during the entry phase of the project. People often asked various questions such as why research was being conducted in Hlabisa and not elsewhere. They also sought clarification about how the research that had resulted in newspaper articles been conducted (Perkins, 1998; Sole, 1998; The Natal Witness, 1997). Most people felt that such media exposure created the false impression that Hlabisa is the AIDS capital of the country (Perkins, 1998). People also asked whether the MRC had a cure for AIDS. Attempts were made to answer the questions as fully and as honestly as possible, but if the researcher was in doubt, she referred the questions to the Community Liaison

Officers, particularly when asked questions about incidents that occurred before her own employment.

There were suspicions about the researcher's real intentions, possibly due to past experiences with researchers, but the presence of the Liaison Officers, who are known and respected within the Hlabisa community, seemed to help in this regard. The standard procedure followed for each interview is presented next.

3.5.2 Standard introduction provided to each informant

Informants were greeted with the necessary titles of respect. Despite the fact that all the informants already knew the researcher from the initial consultative meetings outlined above, and were aware that she worked as researcher/counsellor for the MRC, she re-introduced herself in order to re-establish rapport and facilitate communication during the interview. Informants were also thanked for agreeing to participate in the study and a standard introduction was presented in order to ensure the standardization of the interviews. The standard introduction was designed to inform prospective informants about the nature of study, including how they had been selected, the objectives of the study, the voluntary nature of participation, and confidentiality procedures (See Appendix C).

After it had been ascertained that informants had adequate understanding of the implications of participation, they were then asked to give oral consent to participate in the study.

3.5.3 Translation of the standard introduction into Zulu

Translation is done to ensure that the responses given by the participants are based on their beliefs and feelings about the subject matter; and not distorted by language difficulties. The aim is to ascertain that the target population, which speaks a different language than that spoken by the researcher, understands the research process (Brislin, 1980). This study differed from the usual cross-cultural studies because the researcher actually speaks the same language as the participants, but had to formulate the introduction in English in order to facilitate understanding by both the supervisors and the wider scientific community.

The standard introduction was also formulated in English in order to facilitate the supervision of the researcher.

The translation of the introduction proved challenging. It was further complicated by the use of technical terms such as "informed consent" which do not have equivalent Zulu words and could best be described through the use of Zulu paragraphs. Informed consent was translated as: *ukunikeza imvume yokuba yingxenye yaloko osuwaziswe ngakho,* which literally means giving permission *(imvume)* to be part of that which you have been informed *(osuwazisiwe)* about.

The above translation had to be located within the research context in order to facilitate understanding of the term, whilst retaining the meaning of the concept. The researcher realised that she had to take care, whilst describing informed consent, that she did not unconsciously describe what it should entail, as this would influence informants' responses.

The translation of the standard introduction was also checked by a colleague that works in the Zulu Department of the University of Natal in order to ensure that the meaning had been retained. She gave confirmation that the translated versions retained the meaning of the original introduction.

It was decided that the translated material should be field tested in order to facilitate informants' understanding of the research instrument (Brislin, 1980). The researcher sought the opinion of the Community Liaison Officers with regard to the accessibility of the translated versions. Both officers felt that the translated introductions maintained the meaning of the original.

The researcher decided to systematically read and discuss the standard introduction with each informant rather than ask them to read for themselves, as the level of education varied substantially. This approach was perceived as more likely to maintain consistency with regard to preparation. The researcher was the only person that conducted the interviews. This served to limit possible effects of interviewer bias. It was observed that the informants that were

more educated tended to switch between Zulu and English in their responses. This was particularly done when it was felt that the use of an English term could facilitate understanding. A discussion of the interview guide used after the standard introduction follows:

3.6 THE RESEARCH INSTRUMENT

Justification for the Interview Guide

The interview guide, one of the basic approaches to collecting qualitative data through open-ended interviews, was used to interview informants with the aim of facilitating narrative disclosure about research and informed consent. Patton (1990) describes the interview guide as a list of questions or issues that are to be explored in the course of an interview. This list is prepared in order to ensure that basically the same information is obtained from a number of people by covering the same material.

The interview guide therefore provides topics or subject areas within which the interviewer is free to explore, probe, and ask questions that illuminate the subject under discussion. The interviewer is thus free to build a conversation around the subject, to word questions spontaneously, and to establish a conversational style that suits the respondent being interviewed, while maintaining focus on the issues that have been prepared for discussion.

The interview guide was selected for the present study because it was felt that this approach would enable the researcher to access the perspective of the person being interviewed rather then impose own ideas. It would thus be possible to gain insight into how people have organized the world and the meanings they attach to what goes on in the world (Patton, ibid). Because the issues to be explored are outlined in advance, interviewing across a number of people thus becomes more systematic and comprehensive. One is also able to decide how best to use the limited time available for the interview.

The flexibility of the approach in terms of the sequencing and wording of the questions allows individual perspectives and experiences to emerge. It was also perceived as likely to

enable the interviewer to adapt each guide to suit the very different informants that were interviewed. The interview guide can be developed in more or less detail, depending on the extent to which the interviewer is able to specify important issues in advance. Interviews tend to remain fairly conversational and situational when the interview guide approach is used.

Patton cautions, however, that important topics might be omitted because of the flexibility of the interview guide. Interviewer flexibility in the sequencing and wording of questions might also result in substantially different responses from different perspectives, because the researcher might simplify questions for participants who appear to have comprehension difficulties, and inadvertently guide responses. This would reduce the comparability of responses (ibid).

Patton's concerns about the interview guide were taken into consideration when the interview guide was formulated. The researcher also focussed on the guide in order not to omit salient topics. An attempt was also made to ensure that flexibility in terms of the sequencing and wording of questions did not affect the standardization of the interviews. The interview guide is presented next.

The Interview Guide

After the researcher had read and discussed the introduction with the informant, she then indicated that the interview was about to begin. The tape was then switched on for recording. Attempts were made to minimize the imposition of predetermined responses when gathering data, in order to enable informants to respond spontaneously in their own terms (Patton, 1990).

The main questions A, B, and C are open-ended questions. These questions were designed to explore key informants' perceptions of research, conceptions of informed consent, and projected motivations for why individuals agree to participate in research. See Appendix A for the Interview Guide.

The researcher asked each of the main questions and then gave some time for spontaneous responses. The main questions are followed by the probes, which were asked in order to "...deepen the response to a question, to increase the richness of the data being obtained, and to give cues to the interviewee about the level of response that is desired" (Patton, 1990, p.324).

The Content of the Interview Schedule

The contents of the interview schedule are discussed in this section. Attempts are also made to present justification for the questions formulated. The formulation of the questions was largely informed by the literature in the area, and the information gaps identified.

Section A

The intention of this section was to gain insight into people's perceptions about research, hence the opinion question: "What do you think research is?" It can be argued that Hlabisa has been extensively researched (De Cock & Wilkinson, 1995; Gilks et al, 1996; Wilkinson, 1994; Wilkinson, & Moor, 1996). It seemed necessary to explore how Hlabisa people perceived research and what meanings were attached to it.

There seemed to be a need to explore whether the informants thought, for example, that research means that people are being treated for health problems (Christakis, 1988) and whether they were aware that research could have both risks and benefits. It was speculated that the conduct of past research would largely determine people's responses to future research projects such as HIVNET.

The aim of the probe: "Please tell me about research conducted in Hlabisa?" was to gain insight into any factual information that the participants had about the subject under discussion. Informal conversations prior to the current study led to the realization that media coverage of the HIV transmission rates in Hlabisa had resulted in negative responses among a number of Hlabisa residents. People felt that the article identified their community as the epicentre of the AIDS epidemic (Perkins, 1998), and this resulted in a lot of negative publicity for the community. It was also likely that since the research presented in the

newspaper had been conducted by the Medical Research Council, by whom the researcher is employed, informants would be reluctant to express their unhappiness about how research had been conducted in the past.

A decision was therefore made to use an interactive question in order to facilitate narrative disclosure: "I have heard stories that people are not happy when research is conducted...what would you say about this?" It was hoped that this would enable the informants to realise that the researcher already had some information that there was unhappiness about past research, and this would facilitate a process whereby they would be comfortable with discussing the effects of the newspaper articles.

The interactive question was also formulated in order to combat social desirability responses, which are responses that research participants give to researchers because they believe that is what the researcher would like to hear. Social desirability responses are likely to be given when there is an unequal relationship between the research participant and the researcher. The participant that gives social desirability responses is often reluctant to antagonise the researcher, but wants to gain approval. It was felt that the interactive question would remove the focus from an informant's own emotional response to past research as it refers to an "other".

Section B

This section primarily dealt with the issue of culture and informed consent, hence the question: "Suppose a young Hlabisa woman was to be approached for participation in a research study. Please tell me a story about what should happen?" This question was asked in order to ensure that the informants, who might not have had similar experiences with regard to research and informed consent, could have a common frame of reference. The question was also designed to explore their perceptions about the rights to information of prospective research participants, hence a question such as: "What should she be told?"

The researcher was interested in the decision-making processes that the informants would describe. Matsumoto (1996) and Triandis (1994) suggest that individuals within collectivist

societies such as Hlabisa tend to subscribe to the ingroup, and often consult the ingroup when a decision has to be made. It was therefore felt that it would be informative to explore what people's perceptions were, for example, about a woman who made decisions on her own? Would the informants recommend collectivistic decision-making?

The researcher also wanted to gain insight into the control mechanisms that are exercised "Please tell me a story about what might happen if the above-mentioned woman did not consult with anyone?" This section raised concerns about social stratification in terms of age and gender. It was perceived as essential for gaining insight into the cultural norms of Hlabisa people and the mechanisms put in place for ensuring that these are respected. The researcher did not intend to make generalizations about all residents, but was interested to find out how the perceptions of norms and values varied by individuals and family groups.

Section C

The aim of this section was to explore what Hlabisa people's motivations for participating in research were, hence the question: "What makes people participate in research?" which was formulated to explore the goals and expectations of research participation. It was thought that it might be informative to explore whether or not Hlabisa people felt that their expectations had been met in the past "Have the community been happy with what they have got from research?". The question "Would they like it to continue?" was designed to explore what the informants' opinions would be in terms of the continuity of research. It was felt that it might prove beneficial to explore what the informants' recommendations for future research would be.

3.6.1 Translation into Zulu

The interview was initially formulated in English in order to facilitate supervision and understanding by the scientific community. It was then translated into Zulu (See Appendix D), as the researcher's intention was to interview the informants in Zulu to enable them to express themselves in their vernacular so that their interpretations could be captured at their best. The translation proved to be a challenge, as described in the translation of the standard

introduction, because some English words could not be replaced by any equivalent, single Zulu concept.

The fact that the researcher is a Zulu-speaker from a neighbouring area did, however, facilitate the process as it meant that the researcher had a much better chance of achieving equivalence of meaning.

There were situations where the closest Zulu word to the English one was used with the assumption that one attached the same meanings to the concept as the informants did. An example of how common understanding was assumed follows: "Consult", that is mentioned within the probe that reads: "Please tell me a story about what might happen if she did not consult with anyone", means: "to ask advice from (someone)", (Collins Shorter English Dictionary, 1993). The closest Zulu word: *"ukubonisana"* was chosen. Its direct literal meaning is "to help each other see", but it is often used to refer to a situation whereby people share ideas and give each other advice.

There were concerns, however, that since the researcher came from a different, even if neighbouring, area which has its own dialect, the Zulu words chosen to render meaning might not be the first words that the informants would have chosen. The colleague from the Department of Zulu at the University of Natal was also asked to check whether the translated version had retained the meaning of the original and her perception was that it did. The Liaison Officers also felt that interview guide was accessible. The informants also did not report any difficulties with regard to the accessibility of the words.

A tape-recorder was used during the interviews as mentioned in the standard introduction. This implications of this are explored in the following section.

3.6.2 Tape-recording of the interviews

All the informants gave their permission for the tape-recorder to be used after they had been informed about the reasons for its use. The reasons are presented below:

Justification for the tape-recording

In addition to increasing the accuracy of data collection, tape-recording enabled the researcher to be more attentive towards the informants. It was thus possible to maintain some respectful eye contact with the informants and observe non-verbal behaviour. Tape-recording also facilitated the rapid flow of information. Brief notes were taken during the interviews to enable the researcher to formulate questions about issues that needed to be clarified. This facilitated later data analysis and enabled the researcher to locate important quotations in the tape-recording.

Challenges encountered during the use of the tape recorder

- Discomfort with the tape-recorder

Some informants were uncomfortable about the tape recorder, partly because they were uncertain about who would have access to the information that they were sharing and the impact that this would have on their lives. It is also possible that some were uncomfortable because they had had previous unpleasant experiences with researchers from the organization that the researcher works for. When it was felt that the informant was still uncomfortable about the tape, the researcher reminded the informant that the information shared would be confidential. The informant was also reminded that the tape could be switched off and the researcher would take notes. In addition the informant was reminded that they could terminate participation in the research study without any negative repercussions.

It was observed that some informants gave more crucial and informative material once the tape recorder had been switched off, after the formal interview had ended. This was suggestive of a reluctance on the part of some of the respondents to mention sensitive information on record. The researcher took thorough and comprehensive notes when this occurred.

- Different responses

The informants presented very differently. Some were very relaxed and had a lot of information to give despite the tape, while some were quite shy and hesitant and therefore needed guidance during the interview. The researcher found that the psychological skills that

she had acquired as a clinical psychologist-in-training proved useful in establishing rapport and in directing the interview. It was thus possible to be much more flexible in terms of adapting the conversational style to suit each informant, whilst ensuring that standardization was maintained.

- *Emotional expressions*

The emotional expressions of the informants also varied. Some related painful events in a very detached manner, while others were visibly moved by their past experiences. The psychological skills acquired during training also proved useful in this regard. The researcher was able, for example, to contain the emotions of an informant who became very tearful when she recounted the experiences she and her colleagues had had with past researchers.

3.7 DATA ANALYSIS

The various methods used during the data analysis phase are discussed below.

Memos

The researcher made observation notes after each interview, mostly about how the informants had reacted to the interview, and about how the researcher felt about her own role during the interview. Such information placed the interview in its context, and made it possible to derive meaning from it. Memos also facilitated the provision of meta-comments on the material recorded.

Transcription of the interviews

The researcher made a full transcription of each interview. This process was time-consuming, particularly because the researcher simultaneously translated the information into English in order to facilitate supervision and data analysis. The researcher found that the rich meaning of some Zulu words was not easily translatable to English and when this situation occurred the researcher used the Zulu word and provided, in brackets, English words that were perceived as close in meaning to the Zulu concept.

3.7.1 Narrative Analysis

The initial aim of the study was to conduct narrative analysis on the stories that people told with the aim of gaining insight into how these expressed understanding of research and informed consent. It had been hoped that these could be explored with the aim of facilitating the researcher's insight (Mishler, 1986). The researcher wanted to explore which characters were introduced, what events and relations were introduced, and how their actions were described. There was an interest in the significant conflicts that might be introduced, and how these were resolved. The researcher also hoped to explore what the point of each story and sub-story was.

In order to gain this insight, it was planned that the researcher would pay attention to the familiar triad of linguistic topics, which are the basic issues of structure, meaning, and interactional context. There was also an interest in how the informant connected the several issues raised in the interview guide to provide a continuous and coherent account. The researcher observed how the construction of the story was affected by the interactional setting in which it was produced, and particularly how the narratives were used to express general cultural themes (White, 1995).

Each transcript was repeatedly read with the purpose of analysing the story structure, context, and content. An attempt was made to use the methods outlined above in order to facilitate narrative analysis. It soon became clear, however, that narrative analysis of the transcripts was not really feasible. This was possibly due to the following: the questions used in the interview guide do not appear to have been formulated in a manner that invited informants to tell narratives with characters, plots, significant conflicts, etc. Informants generally gave brief, seemingly factual responses to the semi-structured questions that they were asked. Except for a few narratives told by the hospital employees with regard to negative experiences with research, most responses appeared more amenable to thematic analysis.

It is also possible that the nature of the responses was largely determined by informants' limited experience with research in general, and informed consent in particular. Only two of the informants had participated in previous research, and this had an impact on the type of

responses that they could give. Most of the responses were largely hypothetical, and seemed difficult to present as stories. It is also possible that the researcher, who had limited experience with the narrative approach, could have given the participants more space, and time to give storied accounts on which narrative analysis could be conducted.

Because of the nature of the responses that were given, it was thought thematic analysis would be the most useful method for gaining insight into informants' conceptions of research and informed consent.

3.7.2 Thematic analysis

The thematic analysis conducted was largely informed by the work of Boyatzis (1988). Transcripts of the interviews were reread with the aim of reducing the information. An outline of paraphrased items and synopses was created. Synopses were compared in order to determine similarities and differences. This in-depth review of each transcript enabled the researcher to continuously process the information, and thus facilitated familiarity with the transcripts.

An attempt was then made to identify themes, which are patterns found in given information. This process was largely guided by the questions asked in the interview guide. Important themes from each transcript were identified. It was thought that the information could best be organised by differentiating between main themes and sub-themes. Main themes were determined by the level of importance that the informants attributed to them, and the level of commonality between the informants with regard to the importance of the theme.

Themes were presented as a set of statements that were designed to capture the meaning that informants attached to the phenomena they described (ibid). An outline of what each theme included and excluded was also presented in order to eliminate confusion about the themes. The raw information was reread in order to ensure that the themes and sub-themes were properly identified. Some themes had to be rewritten as it was felt that they did not capture the meanings that the informants had identified. The identification of themes enabled the researcher to describe and organize the information and the observations made.

The researcher's supervisors independently developed themes for some of the transcripts. This was done in order to facilitate the reliability and consistency of the researchers' themes and sub-themes. Some themes and sub-themes had to be changed after the researcher and the supervisor had discussed their differences in opinion. The main themes identified were: **conceptions of research, social desirability, negative experiences with research, informed consent, the role of the family, the role of partners, and the role of the community.**

The identification of themes facilitated the interpretation of the information. An attempt was made to interpret the themes in the context of existing theoretical frameworks and the available literature.

The measures that were undertaken to ensure the reliability and validity of the study are presented below. Attempts were made to ascertain that the study had consistency, and addressed the aims and objectives of the study.

3.8 RELIABILITY AND VALIDITY CHECKS

Reliability/Dependability/Auditability

Miles and Huberman (1994) define reliability as consistency over time and across researchers and methods. The interview guide enabled the researcher to collect data about the same issues across different informants, a range of settings, and different times. Because the issues to be explored had been outlined beforehand, interviewing was systematic, comprehensive, and thus consistent. Data quality checks were made by a colleague that listened to a selection of recorded interviews and compared these with the corresponding transcripts. The intention was to assess whether the meaning had been retained during the translation of the recorded interviews into English. The colleague indicated that the meaning had been retained. the supervisors' independent application of the themes and sub-themes on the transcripts facilitated the consistency and reliability of theme identification.

Internal Validity/Credibility/Authenticity

Miles and Huberman suggest that internal validity is about the truth value of the research material, including whether the findings of a study make sense to the people studied and to readers (ibid). The interview guide facilitated a process whereby the different types of understanding described by Maxwell (1992) were explored:

- *descriptive understanding:* informants were invited to tell what happened in specific situations and were able to do this through the use of examples and narratives;
- *interpretive understanding:* the responses that informants told gave insight into the meanings that they attached to their experiences;
- *theoretical understanding:* informants' responses also indicated that their perceptions, and relationships were largely influenced by the collectivistic conceptions of personhood such as the importance of the family, the necessity for consultation, etc;
- *evaluative understanding:* the interview guide facilitated insight into the judgements that people attached to the value of actions, such as lack of consultation and the impact of that on the family. Attempts were then made to present the results in a manner that could best be understood by the readers and the informants themselves, thus achieving some internal validity.

External Validity/Transferability/Fittingness

Miles and Huberman (1994) assert that external validity refers to the question whether the conclusions of a particular study are transferable or not to other contexts. They suggest that external validity entails determining whether the conclusions "fit" and how far they can be "generalized" (p.110) The interview guide could be used in other communities as it seems general enough to accommodate different settings. The results were also presented in the form of "thick descriptions" in order to enable readers to assess whether the findings have potential transferability, and their appropriateness for other settings.

The findings are congruent with the observations of Christakis (1988) and Gostin (1995) who suggest that there seems to be a need to reconsider the use of an informed consent process as framed by Western principles if one is working with African research participants. It is

unlikely though, that the conclusions could be generalized to communities with different cultural norms and better economic resources. Although some sectors were not represented, the sample group was diverse enough for the findings to be generalised to people in leadership positions within a context similar to Hlabisa.

3.9 LIMITATIONS OF THE METHOD

This section explores the limitations of the method. The limitations of the sampling procedure will be explored first, and the implications of different levels of comprehension will be presented next.

Limitations of the sampling procedure

The limitations of the sampling procedure, described above, indicate that representation was probably not sufficient, and this may have resulted in information bias. Sectors such as the Department of Agriculture, might have been included for better representation. It might have also proved beneficial to interview more representatives of the business, welfare, and protection services for further input. Representation is, however not the main issue in purposive sampling. This type of sampling is primarily designed to obtain rich and diverse data. Diversity was obtained, and this proved very informative. It might have proved informative to interview some young women that had participated in research before, as this might have given more insight into actual experiences of research participation.

Different levels of comprehension

It is likely that the interview guide was biased in favour of relatively more educated informants. Although difficulties with comprehension were not a major feature for the informants that had a lower level of education, it was sometimes observed that some of them required some guidance.

3.10 ETHICAL ISSUES

The aim of this section is to consider the ethical issues that the researcher took into consideration.

Assumptions

Attempts were made to ensure that the researcher did not assume understanding of the informants' cultural beliefs on the basis of being from a similar racial and linguistic background. Interviews were thus approached with an open mind.

Ethical procedures followed

Because the researcher conducted the study in her capacity as a researcher/counsellor for the Medical Research Council, which is affiliated to the University of Natal's Medical School, the study was submitted for ethical evaluation to the Ethics Committee of the University of Natal. The Committee found it ethically acceptable and gave permission for it to be conducted.

The researcher also approached all the sectors in the area in order to gain entry in a respectful manner. Several community meetings were also attended in order to facilitate the entry process, and enabled the researcher to share ideas with residents and thus gain insight into their way of life, whilst maintaining some objectivity.

The researcher also continuously scrutinised her own motives for the research and ensured that the informants, and any interested members of the community were aware of what these were. It was also borne in mind that some informants might have been initially uncomfortable with the researcher, as she is employed by the Medical Research Council, the organisation that had conducted the research that some Hlabisa residents perceived as controversial. The informants were told that any information they gave would be treated with confidentiality. The fact that the researcher continuously travelled with well-known and respected Community Liaison Officers helped alleviate people's fears.

The informants were also informed that the researcher would give the informants feedback about the results of the study. An informal agreement was made that should the researcher wish to publish the information for non-academic purposes, all identifying information, including the name Hlabisa, would not be used. Informants felt that this was necessary to

ensure that Hlabisa did not receive more negative publicity. This promise has been kept even during conference presentations on the study.

Informants were informed about the study's purposes, strengths and weaknesses. They were also asked to give their consent to participate and were continuously reminded that they could either switch the tape recorder off or terminate their participation without negative repercussions.

3.11 CONCLUSION

The methodological procedures of the study have been presented. It was indicated that only people occupying influential positions within the Hlabisa community were approached for participation.

After oral consent to participate had been obtained the for key informants, interviews were held with the intention of gaining insight into key informants' conceptions of research and informed consent. It became clear, however, that the planned narrative analysis of interview information was not really feasible. Thematic analysis was then adopted as a better option for capturing meaning attached to research and informed consent.

Although the research method had some limitations, the exploratory nature of the study facilitated better understanding of cultural conceptions of research and informed consent. The main themes and sub-themes of the study are considered in the following chapter.

4. RESULTS

The results of the study are presented in this chapter. The main themes are presented in bold font, while the sub-themes are presented in italics. An attempt is made to provide information on the relative importance that the informants attributed to the themes and sub-theme. Excerpts from the interviews are used to illustrate a particular sub-theme. Some excerpts are provided in Zulu as it proved challenging to find equivalent English words that would retain their rich meaning. An attempt is made, however, to provide English phrases that compliment the retention of the rich meaning of the Zulu excerpts. Meta-comments are also provided throughout the results section in order to give insight into the researcher's perceptions during data collection and analysis.

4.1 CONCEPTIONS OF RESEARCH

Although most informants were initially reluctant to express their definitions of research, they provided various conceptions that seemed to be informed by their past experiences with research:

Research involves information gathering

Most of the informants described research as an information gathering process:

> Research is about finding...the foundation or essence of something
>
> *...lusho ukubuka isimo noma into ethile...uyibhekisise* (...means to look at a situation or at something.... look closely at it)
>
> Research is an in-depth investigation about something happening in the community. It is therefore about finding out how it happens and to whom it happens
>
> In my opinion it is a search that helps one find details about things that affect people's lives, particularly in the lower socio-economic level...
>
> Research is a search for something...a result, maybe like doing an experiment, so that you can get the result of something you are looking for. It might be the results you are expecting, but it might also be something you are not expecting

Research involves problem-solving

About half of the informants described research as problem-solving, particularly in relation to HIV/AIDS:

> Research is a search on problems that are seen in the community. It is a search into how big a problem is. Also who does it injure? What type of person is injured and how much and also if there is no cure.

Research as development

Some informants suggested that research entailed social development:

> ...research..is one thing that facilitates community development..when research is done there is often an objective that the researchers are seeking to assist the community with, such as developing the community in different levels such as health, welfare, etc...

Ignorance regarding research

A few informants mentioned that some Hlabisa people did not know what research involved:

> ..there is ignorance regarding what research is

Research is education

A few informants defined research as a process whereby people are educated about something:

> Research is a process whereby people are ...advised about mistakes...

> Research is distinguishing between good and bad things that happen in communities. Good does not go with bad and sometimes people do something without knowing, including doing something thinking it is good when you are actually doing something bad

Knowledge about past research conducted in Hlabisa

HIV/AIDS research was the most frequently reported research as more than half of the informants indicated that they knew about it.

> There is a lot of research done in Hlabisa, particularly research on AIDS...

A few informants referred to research into electricity and water that was conducted by the Transitional Local Council. Fewer informants mentioned the education of traditional healers , and tuberculosis research. One informant referred to the research conducted by the Welfare Department. Two informants indicated that they had no knowledge of any past research conducted in the area.

4.2 POWER DIFFERENTIALS

It appeared that some informants were reluctant to admit knowledge of HIV/AIDS research, but later made comments that only applied to HIV/AIDS research. For example, one informant who had said she only knew about water research, later said people had reservations about research because Hlabisa residents feared being broadcast on television as living with AIDS. There were many other subtle revelations of denied knowledge.

It was thought that one of the reasons why some informants appeared reluctant to admit knowledge of HIV/AIDS research was that they were reluctant to comment negatively about past research to a researcher employed by individuals working for the organization that had conducted the research. The reluctance was possibly out of fear to embarrass or antagonise the researcher. It is likely that informants were uncertain about who would have access to the information they gave; they may have been concerned about possible repercussions of participating in the current study.

Some informants gave responses that were indicative of a need to gain favour with the the researcher:

> I think research is something that is of great help in everything, if you think about it and you look around, and compare, research reduces a lot of difficulties...

> Research...we often refer to it as an investigation of things that are straight, and the straightening of those that are not straight

> *...imfundo nabamhlophe ibona abageza imiqondo yethu ngoba phela ukuze ngempela kubekhona ukuhlanzeka, kwenziwe imfundo nabamhlophe beseluleka...uma kelokho singakwemukeli kobe kusho ukuthi asiqondile ukuthi sithole ucwaningo* (education and white

> people are what cleanses our brains...because cleanliness exists because of education and white people advising us..if we do not accept that it means we do not intend to get research)

This comment is indicative of a belief that white people made it possible for blacks to develop.

Some informants indicated that researchers could tell prospective participants anything they wished to tell them:

> ...and I say no matter what you tell them, I don't think anyone would refuse...

The above is indicative of a hierarchical perception of research as the informant seems to assume that people should accept anything that they are told. It is possible that the informant thought that this is what the researcher wanted to hear.

Suggestions were also made that people might agree to participate out of gratitude for the conduct of research:

> ...because if it somebody who pays attention, that person would thank you endlessly and say: you have helped me by bringing research like this...and say thank you...

Some informants demonstrated an awareness of the power dynamics that exist between researchers and prospective participants. They recommended that the researcher bear in mind that some prospective participants were likely to give consent to participate in research out of fear to antagonise the researcher:

> Others think that when it is said they should agree...there is submissiveness...one agrees to something not because they want to but because they are scared to oppose the situation that has already begun...of research

The above comments highlight the power dynamics that exist between researchers and research participants, which are likely to have an impact on the voluntary nature of informed consent.

4.3. NEGATIVE EXPERIENCES WITH RESEARCH

Various reasons were provided for unhappiness about research and these are presented in this section.

Lack of information about research and researchers

Most of the informants felt that unhappiness about research was due to lack of information about research and researchers. Informants suggested that:

> People are never happy, especially if you are not known in the community...

> What I have observed is that the community does not have any knowledge...there are very few people who have the knowledge...maybe the top figures who know that this happened for this reason. The community...there is a need for them to be told and educated..

> ...it was found that research entered in a manner that people were not aware of. The doers took advantage of the fact that people did not know and the results were not well received. Most people did not know and only got to hear about it in newspapers that they had bought that told them about research done on Hlabisa people...

> Ehh...it might be the truth that people are sometimes not happy. What I have observed is that this happens when people have not really been informed about what the purpose of research is and how people are going to benefit from research

Very few informants suggested that people know about research, but rejected it because of ignorance:

> If you don't know what research is, you are like somebody that doesn't have a toilet at home...and still goes to the mountain. That person is still unenlightened, because research is necessary...it brings light, it makes right.

Misconceptions about the research topic

Some informants reported that unhappiness about research was also due to the fact that the research topic, HIV/AIDS, is a topic about which most people have misconceptions. A few informants mentioned that there was still an ongoing debate about whether HIV/AIDS exists or not:

> ...people have got different opinions, some believe that it exists and others don't believe
>
> They keep saying: Is there a disease that is incurable...there is nothing like AIDS.
>
> They have got this thing that : Whites do not want us to spread...they don't want us to give birth to more children and spread as a population...

The ongoing debate seems to be fuelled by people's perceptions that HIV/AIDS is just another example of the government's mechanisms for population control. This also seems to be influenced, to a certain degree, by the fact that most of the informants lived in the apartheid era when fertility control was used to curb the population growth of black people. There is therefore a fear of ulterior motives in research conducted in the area.

There were indications that there is a generally poor understanding of the nature and impact of the disease:

> What is also problematic is that our people do not really understand HIV/AIDS. They think that if one has HIV one can't bath with their face-cloth and they also think if you have HIV you are treated like the people that are mentioned in the Bible and a person thinks that he will be thrown in the forest, and that he will not have any contact with her family. This might then cause a person to be reluctant about research

It remains questionable, however, whether people's fears that they would be treated like the lepers in the Bible is a misconception or an accurate assessment of reality, given the stigma that continues to surround HIV/AIDS transmission.

A perceived lack of preparation for the implications of research

Some informants, particularly those working in the hospital, admitted that some research information had been provided, but they felt that this did not adequately prepare people for the implications of research:

> Sometimes you find that there has been some communication, and you find that it has been mentioned that there will be research, sometimes even letters are released here that say that in a particular ward research of this and that nature...For others it doesn't click and when it is

> done, she has forgotten and sometimes when something is done the reality doesn't become what one was expecting...

This appears to have resulted in a situation whereby people are very uncomfortable about research and would like more information:

> ...if people do not know something..eh..if it comes from outside..everybody does not feel comfortable or relaxed about it. If somebody does not feel relaxed, she or he cannot co-operate with that which is making him uncomfortable...people now want to know who you are, where you are from, who has sent you, and what are you doing. But if they know who you are and they see that this is going to help us...people relax

Negative past exposure

Some informants mentioned that the unhappiness about past research was due to past exposure. Informants referred to the media presentation of Hlabisa HIV transmission rates as high. This had resulted form the fact that Hlabisa was functioning as a sentinel surveillance site. Nonetheless, most informants felt that the publication of the HIV status of their community gave the false impression that Hlabisa is the AIDS capital of South Africa (Perkins, 1998).

> There was then a lot of bitterness that Hlabisa was presented as a place that is full of AIDS...as if the whole community had AIDS. When it is not actually like that..it was just that research was reported here...almost every case was reported. Unlike other places which I think are similar to Hlabisa but maybe there is no one reporting there in the same way

Some informants indicated that they had the perception that the statistics presented in the newspaper were not a true reflection as there had been no comparative research done. They also felt that the article stigmatised the community. Such nationwide negative exposure appears to have resulted in fear of researchers.

The fears described below have resulted in reluctance to participate in research.

People fear that research results reflect on one's moral character, including that of the community:

> Because it is a disease that was initially emphasized as a disease that you get if you do not behave well (promiscuous) ...most people fear that it will be said that I did not behave well. So because of that people distance themselves

> ...you find that you don't really know whether something is required of you or maybe something that will be found in you will make you seem like people *abangamile kahle* (literal meaning is not standing well, but refers to bad moral character in this context)

> ..because it (HIV/AIDS) has been perceived as something that is a shame...now people talk behind closed doors if someone has got it. So research means that this person ends up feeling exposed, and that people will now know about her situation and she will be reminded constantly

It is felt that researchers disclosed information about imminent death:

> They are scared to accept that there is a disease...if you mention this disease straight away that person sees death

> ...it is a truth that cannot be opposed that when you have the AIDS disease you can no longer live for too long...yes

The need to work on people's fears and encourage people to accept themselves and that which is unacceptable was emphasised by the spiritual healer. She also felt that informing people of their imminent death goes against religion:

> ...even in the Bible when the Lord created Man, He hid the time for leaving. Now research exposes that if you have the disease, you then know that you won't live...This often places people in an unpleasant situation

She indicated that there was a need for people to be informed about God's love for them, and encouraged to get closer to Him before death.

Some informants indicated that some people attribute HIV/AIDS transmission to bewitchment:

> They only think that someone has been bewitched by somebody and that is all

> You find that if a person has died it is said that person was bewitched and others in the community say: it will now be said that there is AIDS, even if a person has bewitched my child it will be said that it is AIDS

A few informants indicated that some people believe that the feared exposure of people's HIV results enables evil neighbours to realize that their *muti* (which means a traditional concoction that has supernatural powers which may cause misfortune for the person for whom it is intended) has worked:

> People are always not happy about their health being known...a person does not want it to be known that they are sick, because they have the belief that other people are witches that bewitch. Maybe if a person knows that you are sick, she is then happy...

The informants seemed to be making an indirect request for researchers to take the cultural beliefs of the area into consideration, in order to ensure that people feel protected.

Negative impact for the hospital

The informants employed in Hlabisa Hospital felt that exposure of the HIV/AIDS transmission rates in the newspaper had negative implications for the Hospital as the research had been conducted there under the auspices of the Medical Research Council (Perkins, 1998; The Natal Witness, 1997):

> ...this made them very scared now that if you went to Hlabisa ..some even said that if you go to Hlabisa Hospital you are just told that you have AIDS.

The informants suggested that Hospital employees felt very strongly about the impact of media coverage of Hlabisa's HIV/AIDS incidence and prevalence rates. Some employees took a pro-active stance:

> We did not hide the fact that we were hurt, and we asked whether people, even if they were sick, had been told that they would be the laughing stock in the newspaper. Even if they had not seen the paper, other people would have seen it and their lovers would see this...

Hospital employees felt very strongly about the implications that media exposure would have on patients' lives.

Ethical standards were not complied with

The informants working in the Hospital reported that what had also made people upset was that ethical principles had not been complied with:

> There was a lot of noise when bloods were taken, it was an anonymous test but...there were sometimes situations when some note-taking was done and people were not happy about this. Maybe the manner in which counselling was done...maybe counselling was abrupt...for someone to make the correct choice.

One informant reported feeling hurt and angered by what she perceived as being undermined in her professional role as a member of a Research Ethics Forum. She reported that the situation was exacerbated by the arrival of an overseas researcher who claimed that she would be researching Hepatitis B among patients, but did not mention the main focus of her research, which was HIV/AIDS. The informant mentioned that they were hurt and confused:

> We even asked ourselves what our presence in the forum meant...what did our presence in the forum really mean? ...*Sasiyizilima*...(we were just being fools)

She added that:

> Things were finished...when even the structures that united all of us with the intention of us being part of the set up, knowing what is going on, helping and advising when a mistake was done, were disintegrated...when it became obvious that there were things that you really wanted to know how they came about...

She suggested that they had been sidelined because of their assertiveness. They were also very unhappy about the blurred boundary between being a doctor and a researcher. There was a feeling that most doctors (who were British) had come to the hospital solely for the purpose of

conducting research, and would conduct research after hours, without informing the sisters-in-charge, and obtaining permission from the patients. Some hospital employees then decided that no more blood would be taken from patients, unless there was clarity about the intentions of researchers.

This informant felt so strongly about how research had been conducted and the negative impact that it had on the community that she cried during the interview. The researcher tried to contain her emotions by suggesting that it appeared as if she had adopted strategies that she felt would prevent further damage. Suggestions were also made about how she could use the support network that she felt she had within the hospital.

Fear of exploitation

The lack of information about research, and subsequent negative exposure appears to have fuelled people's fears of exploitation by researchers:

> Some just think that the researchers are just playing with them and there are things that they want from us...with which they will use to satisfy their own needs. The perception might be that they are just being exploited when research is conducted...

> Research...is also not easy for most people...because it then seems as if an experiment is being done with her and she is being used. She is the one who is being used for something to happen

The term "experiment" has strong implications in this context as it suggests that the informant felt that Hlabisa people are being used as guinea pigs.

The political history of the area also seems to contribute to the fear of exploitation:

> ...there are people who have remained with the wounds of political unrest..so if there is somebody in the area *ozofokisa.* (literal meaning refers to one who has come to sniff the air, but refer to one who has come to establish the dynamics of the area in order to pass that information on in this context)...that means that person has come to campaign...

> Maybe others look at it with a political eye and they then think: oh another organization is now going to enter into our community and we don't want that organization. They now want to rule us with this organization

A few informants also indicated that people feared that research would have a negative effect on their living circumstances:

> ..when something is found here, maybe if gold is found here, we would be removed from this area, maybe we are cultivating on it and we get food from it...we would then be sent to an area we do not like...

One informant mentioned that people feared that research would interfere in what they hold fundamental within their culture, including their relationship with ancestors:

> Also, others are not educated enough in order for them to accept any new changes that come. It is very hard to accept new changes, because even with the arrival of electricity, they were saying: our ancestors will no longer be present because there is now electricity in this home..

Concerns were also raised about research benefits for the Hlabisa community. There appears to be a difference in opinion as some people felt that there have been no benefits, while others felt that the community has somehow benefited from research. The remaining informants felt that people were divided on whether Hlabisa had benefited from the research or not.

Some informants felt that past research had resulted in some benefits for the Hlabisa community:

> Sometimes there is some happiness, like in T.B. This programme helped in that people were asked to participate and community members helped make it (the possibility of staying in hospital for six months for T.B. treatment with fewer hassles) happen

Some informants indicated that there was division with regard to whether research had been beneficial or not:

> Some are happy, but others in other areas are not happy because water has not yet reached them...

> In my opinion, many would be happy, but then many others would not be happy because they would not believe that this research will help them...or maybe they are just being lied to...

Some informants raised concerns that Hlabisa had not benefited from research:

> There was...a lack of trust and a little bit of doubt that when all of this is done, what does Hlabisa get?

> Another problem is that why is it that blood continues to be taken and you hear that someone has written a paper, someone has done this, what are we getting as the Hlabisa community?

> ...if you consider the fact that these are people we are working with, and this is painful to them....and you do not really know what these people can say they got from research

> The problem with HIV research is that there is nothing yet tangible, it is just continuing, and people want to know: once I have been checked what will I get, how will it help me?

A few informants suggested that rather than result in benefits, research had resulted in losses:

> Research reminds a person about the results and I think sleep does not come easily at night when you have really heard that you maybe have the disease

> I think others are not really happy, because I think if somebody has been researched and it is found that she has a particular disease...you find that you no longer have integration with other people and you find that you are isolated

> There is something that I have heard that people are sometimes researched when they are in hospital and you find that a person has the disease and it is then said she will not even get pension money and insurance says it will not give out the money...the person loses rights through research.

There appears to be a need for more clarity about research benefits:

> They do want research to happen and they can get help, but they wish it would be something you could just tell them about and say here it is...they don't know what the side-effects are like

Informants also differed on whether research should continue or not. Most informants mentioned that there is division about whether research should continue or not:

> *Abantu abayi nganxanye bengemanzi* (people never go to one side because they are not water). There are those that would like that and those who do not.

Decisions about whether research should continue or not appeared to be largely determined by whether one had information or not:

> ...there are those that now have the information who might say it should continue and there are those that do not have any information who do not want any research to be done in this area.

A few informants indicated that people would like research to continue. They suggested, for example, that people had re-framed the HIV/AIDS experience as it was felt that HIV/AIDS research had resulted in benefits:

> One said: you know HIV/AIDS has helped many people. Look at so and so, she had no job and as soon as she got this disease, she was employed. She has built a house for her family and has done many things and there is nothing...with which you can say this person has a disease...there is hope that if something is done, people will tend to accept it.

> And recently, as people are talking about Sosobala and saying that AIDS is curable...people are becoming more relaxed then before, that at least, maybe I myself cannot afford, but the generation that I would give birth to will hopefully not be finished by AIDS

A few informants suggested that people would not like the research to continue. Some of the reasons for this opinion was fear of being informed that one had AIDS, and thus knowing that one did not have long to live. Informants' conceptions of informed consent are presented next.

4.4 COMPONENTS OF INFORMED CONSENT

Informants gave varied responses to the questions on informed consent. Their views, which are presented below, are discussed under the following components: establishing a relationship, motivation, consultation, decision-making, and actual consent.

Establishing a relationship

Some informants emphasized the importance of establishing a relationship between the researchers and the research participants during the informed consent process. It was felt that the relationship could be established through the mechanisms described below.

One informant emphasised the need for respecting one's *ubuntu* (which was defined as respect for another person's personhood or dignity. This concept is different from *the* commonly used*ubuntu* that refers to humanity towards others):

> ...there is a danger that her personhood will be affected because no matter how ill a person is, I am convinced that even if a person has got this disease, your being a person means you should be treated with dignity because a disease does not change your being a person

Some informants suggested that the following would facilitate the establishment of a good relationship:

> Firstly it is important...you told me in the beginning that every answer is right and this builds confidence...then one can see something in anyway...but what I am saying is being said by me and I am welcome...

> If someone is going to be researched there is a need for that person to be talked nicely to...

> A relationship is important because even when you are talking to people and a person can see that: I am talking to a friend or a relative that loves me...the fear becomes hidden and you end up feeling relaxed

> I think the approach of the people conducting research must be open..like you, say, you are travelling with Baba Jobe...they then see that o.k. this is somebody we know so we are unlikely to be given information that might not be good for us...

> ...researchers have not yet given themselves the opportunity to visit homes..they should then enter house per house because people are sitting on a lot of ignorance

> People should be told the truth. Nothing must be hidden. People must know the truth.

> As a researcher...you must be a good example, you must practice what you preach

Total respect for one's ideas and cultural context, friendliness, honesty, and accompaniment by trusted community members, were identified as necessary for establishing a good relationship between the researcher and prospective participants.

Information about the research project

Most of the informants emphasized the importance of educating people about research as the dominant perception was that people were not well informed about the purposes, benefits, and risks of research:

> I think people should again be educated about what research is...and also the fact that they would not be affected in anyway, because a person might say: what will happen to me

> ...a lot of time should be dedicated to educating. You see time for educating so that by the time you get here people will really know. There must be nothing left behind..

> If someone is going to be researched...there is a need for that person to..be advised about mistakes...tell her that AIDS exists and it happens a lot..

Some informants also emphasized the importance of informing people about the motivation and goals of research, the type of people required, and the possible impact of research:

> ...they should be told why there should be research, including what is happening?..they should be told about the goals of the research...they should be told what type of people are required for participation in research..

> What is needed is that this person be given information regarding how research will impact on him/her...secondly the person must be told how far privacy will go within research...

Whether the proposed research would result in benefits for the individual and the community or not, seems to be a major parameter for determining participation:

> ...the person should be told who this will help...whether this will help her only or whether it will help other people as well..if the research is probably going to use injections...how will these side effects affect her?

> ...the female that is being approached should be told what she will be working on...and how this will help her and how the community will benefit..so that she can be positive about it and be able to explain to other people...

A few informants suggested that the economic situation be taken into consideration during the education of people about research. It was mentioned that researchers should realise that most Hlabisa people suffer from unemployment and starvation. Researchers, who are often in a better economic situation, are therefore likely to be perceived as making a living through people's pain. It was recommended that researchers should really inform people about research, particularly about its purpose, benefits, and risks, as this might help reduce suspicions.

Understanding

Most informants suggested that the researcher should attempt to understand the participants context. It was strongly recommended, for example, that researchers should consider that AIDS is a stigmatized condition that is perceived as taboo to talk about:

> ...this community is very quiet about this and no one is prepared to talk about this...if there is a way for them to go privately, I believe they would go

> ...when a person is told that she has the disease, ...*abewuwafawafa* (literal meaning: one that dies many times but used to refer to a situation whereby somebody just keeps quiet and keeps something to herself) and just resolves to spread it and says she does not want to die alone

> You first have to convince them a lot, ...it is just that in AIDS it goes with a loosening of morals *(ukulahlekelwa isimilo)*, somewhere. It could be my partner, it could be me, but we don't know, all we know is that it means you have AIDS and it means you slept. You see. It is associated with sex, and our community is never open about sex...

A few informants encouraged the importance of facilitating understanding during the informed consent process, particularly within an African community that had had minimal exposure to the dynamics of research until recently:

> ..we are still far back, things were done faraway and we hear of them by hearsay, and it reaches us when people come and just inject us and give us tablets, which have already been researched faraway and this is still a new process for us that people come to us and try things out and it sometimes seems as if: Oh they have come to do things with us

This informant indicated that researchers must realize that people within the community are likely to be submissive where doctors are concerned:

> ...our people are very quick to say: Oh it is alright whatever the Doctor has said...It should therefore be your duty to emphasize..make the person sit down and understand and satisfy yourself that the person has heard well because later this will become a problem..It comes back...it backfires...

She stressed that it was necessary that the researcher ensured participants' understanding and did not become too eager to finish the informed consent phase:

> There will be a need for her to be talked with so that she could clarify because you sometimes find that people take things easily and just rush for you to do what you wish to do and you find that she has consented to something that she probably did not hear well and when the results come out it becomes a problem and then the person realizes that she put herself in trouble...

> Sometimes you find that a counsellor or researcher is happy that the person has consented only to find that the person did not hear well what was being said...and this later causes problems...and it seems as if the researcher has put this person in trouble and the person got robbed in some way

The use of anticipatory questions such as how a person would take a positive HIV result, was encouraged in order to broaden understanding of the implications of research and mobilise support.

Decision-making

A few informants described decision-making not as a once-off incident, but a shared decision-making process:

> It is not something I can talk about with you now and then make a decision but it is something that we should talk about and be given time...it is something that I really need to think about and ask myself whether I would really like to participate...And do I really feel comfortable? ...and talk again and be given time and then I reach a decision for myself

Timing was also described as important. Decision-making was also described as dependent on when somebody was approached.

Some informants felt that personality characteristics influenced one's decision to participate. It was suggested that a well-mannered person was more likely to participate in research:

> Those people should be well-mannered. It should be a female who lives well with her family...because if she does not live well with her family...even when researchers come to this home you will not be relaxed you will know that ...*lababantu bahlalisa okwezingwe* (these people live like leopards)..eh..nothing will therefore proceed

One informant indicated that some people were likely to participate as a result of the belief that participation was the Lord's purpose for their lives:

> You might find that she just makes the decision, because the Lord has revealed His future plan to her...It might be that the Lord had predetermined that this person would be the one who would find the cure for this disease

All the informants referred to decision-making as a consultative process whereby the prospective research participant consulted with the researcher, the family, and community. One informant mentioned, for example:

> She will make the decision when she reaches a conclusion about whether she sees the research as likely to be useful...to herself and the community...

Informants were therefore suggesting that a good relationship between researchers and participants, including the transmission of information about anticipated benefits for both individuals and the community, were likely to influence a prospective participant's decision-making.

Actual consent

A few informants felt that the prospective participants could give different types of consent, oral and written:

> Maybe she might say orally: yes I agree to be part of research

> Eh..in my opinion she might make the decision by having a form that she could look at... maybe if there is a need, she could fill that in and sign. If it is something that might affect her life, there might be a need for her to look at it legally and say: I have committed myself to doing this and that...even if something happens to me I don't have a problem...

It remains questionable whether the majority of prospective research participants would be able to read the form, particularly in light of the high levels of illiteracy that exist among black South Africans (S.P.A Consultants, 1994).

Consent to participate was described as likely to be determined by the nature of the relationship between the researcher and the research participants. If this relationship was perceived as honest, respectful, and informative; prospective participants were more likely to give their consent to participate in research. It was also felt that the researcher should be well informed about the topic to be researched in order to facilitate understanding:

> The prospective participant must be approached by...someone educated who knows things, maybe about health for example, who knows very well what research really is, what is vaccination and people must really explain to her so that she hears really well before she agrees

The importance of using anticipatory questions to ensure that prospective participants understand the implications of research was emphasised.

> It is important as a researcher to ask: suppose we are doing the research and we find that, like AIDS, that you are positive, how would you take that?

It was felt that participants' understanding of the implications of research participation would ensure that participants give informed consent. Suggestions were also made that prospective participants were more likely to give consent to participate if they had information about anticipated benefits. Motivation for participation in research is presented next

Motivation

All the informants mentioned various reasons for participation in research.

Some informants felt that anticipation of health benefits made people participate in research. There were, however, differences in opinion with regard to whether perceived infection made one participate or not:

You see the people who will not be scared of this research are people that know very well that they are not affected

It might be someone who has possibly been affected by something

Some informants felt that people participated in order to confirm or disconfirm their suspicions of already being HIV positive, in order to receive treatment if already infected:

...it sometimes happens that the person being researched was already sick and had a suspicion and this becomes an easy way of finding out whether what I was suspecting really exists or what?

Eh...I hope others agree because they have the wish that the disease be conquered. Eh..if they have the wish to conquer this disease. Others agree maybe because the person does not know if they have the disease and the perception is that I may be helped if I already have disease.

...also because she will also benefit in that she will be checked up and if she has curable diseases, they will be treated

A few informants thought that people participated because they were unselfish and were concerned about their nation (altruism):

A decision might depend on whether the people on whose ears it falls have a conscience or not, it might also depend on whether the person who hears about it feels for the nation, if it is something that affects the nation, it might involve feeling sorry for the nation and deciding to help the nation by sacrificing oneself, by possibly making the decision

I think it is somebody who is not selfish...because as this research is being done, it means there is something going wrong, maybe there is something going wrong that should be put right, if she does not think for herself only, and tells herself that I am myself and I want to live in this world, I don't care that there are other people that will get bothered....*uma loyomuntu ekhulile ngomqondo* (which literally means if that person is grown up in the mind, but is refers to being mature in this context), she will know her basic needs...what to do in order to make this happen...family basic needs: she must look into what role she can play in the family. Community basic needs: what she could hold over there

The above comments are indicative of the perception that an individual should put the interests of the nation ahead of individual interests if the need arises and that this is indicative of maturity.

A few informants felt that people participated in research because of the anticipation of economic benefits:

> I think people would agree mostly if they are going to get something, because people now ask: If I do this, what am I going to get, because they no longer want to do anything for free.

> ...the person has a hope that maybe there will be some money that a person might get...there is no work available and a person then thinks: If I agree they might remember one day to include me if an opening occurs

> ...another person does go to research...because she is hungry and wants food...you must remember that in this community people like to dress up in pretty things...

A few informants felt that anticipated educational benefits motivated people to participate in research:

> ...because people benefit in many ways, through knowledge, as they are told how they should conduct themselves, and they then benefit. Sometimes, if you have something that you don't really understand, they tell you: go to a certain place and you will probably get help

> ..I think that a particular person gets help, as I know that there are many diseases now, and I know that so and so once advised me and I know that she might help me if I have an illness of some sort that is not treating me well

There are various reasons for participation as indicated above. Although some of the reasons for participation seem to be individualistic, most of them seemed to be largely influenced by anticipated benefit for the individual's family and community. The role of the family in the informed consent process is discussed in the following section.

4.5 THE ROLE OF THE FAMILY

All the informants stressed the importance of consulting one's family during the informed consent process.

Reasons for family consultation

A few informants mentioned that parents should be approached first during the consent process:

> We can start with the parents. Parents should know that this is going to be done by their children. *Uma sekungene emithanjeni yabo* (which literally means once this has really entered their veins, but is used to refer to accepting something fully in this context), I myself would take my child because I have heard very well what is required

It was also suggested that parents could play an educative role:

> Mothers should be approached first so that they can play a large role in educating their children so that they can relax and state their opinions, because if the children have not been set free by the mothers, they will not be keen to do that

Some informants felt that the family was entitled to information about participation:

> ...the family must know what she is doing as a member of the family...the family must not just be surprised by seeing her do things that cause the family to be upset

> ...the family must know that our daughter has been taken by some people for research and is doing this and that...that is going to be useful in the community in a particular way

Other informants indicated that informing one's parents was expected within the African ethos:

> ...but in rural areas like ours, parents place a lot of importance on knowing that their child has done this in this and that way...and have a say on that and give permission for her to do that even if she is old

Most informants suggested that failure to inform the family would be perceived as going against the African tradition:

> She might make the decision, she is grown up enough, but, by nature, ..it is our African way of doing things, that you can not make a decision without having talked about it at home, in your family, you must help them see why, even when they do not see why, you should help them see

> It is very important that the person really understands her family well...she must not make a decision alone when she had to include her family but it is important that the family be included because sometimes you find that someone takes the decision alone here and then later you find that the family has a problem

> It is important for the family to know that she is going to be part of research because they are the people she lives with, that she is in touch with a lot, such that if anything happens to her the family will be affected in some way...

Some informants felt that the researcher should play a directive role and indicate that the prospective participant should inform her family about the research:

> ...it is also important that the researcher puts this very clearly to the person to be researched...that she must not make a decision alone when she had to include her family but it is important that the family be included

Benefits of family consultation:

More than half of the informants mentioned that there were various benefits of family consultation. Some informants suggested that family consultation facilitated spiritual help and guidance:

> Ehh...before a decision is made this must be a person who has asked other people to help her, you see...As an example if it is a person who is young and still under her parents...and ask for spiritual help and guidance into the how and guidance that will enable her to relax about whether this is not against her religion and against society's norms...she must inform her parents and find their opinions before she makes a decision

Some mentioned that family consultation facilitated support for the prospective participant:

> ...I need my family before taking a decision. I should know that there are some things that I will reach that will depress me and when I am depressed it is the people I live with that should lift me up...

> ..it is better if she tells her family and inform them that this is going to happen so that the family might then become a part of this and support her and assist her in that so that it becomes a success

It was also mentioned that the family also encouraged participation in research.

A few informants indicated that there were benefits to respecting African tradition:

> ...according to a black person's way of life it is up to her to take a blessing from home, that we have freed her to do this

Although the informant who made the above comment indicated that the family could not block participation if there had been no consultation, she mentioned that it was expected that one would inform one's family and receive blessings and good wishes from them. One informant suggested, however, that family consultation was not unique to African culture:

> I think in all cultures there is the fact that you can't always be asked about things that your family does not know about

Family consultation as determined by the prospective participant's preferences

Some informants suggested that the family consultation depended on the individual:

> ...it is up to her whether she tells her family or not, because there is nothing that will affect her family. It depends on her because some people report everything that they do at home, others are selective..but if a person feels that it is important that they tell her family, it is her right to tell her family. If she also realizes that it is her right to go there for her own personal gain, that is also alright, because this will not cause any damage for her family

A few informants mentioned that decisions about whether to consult or not are sometimes determined by the nature of the family, as some families are autocratic while others are democratic. These comments challenge the suggestions that family consultation is perceived as a norm that should be complied within the African culture, for things to proceed smoothly. Further challenges to family consultation are discussed in the next section:

Challenges to family consultation

A few informants indicated that family consultation had its challenges which are described below.

Definitional challenges

One informant mentioned that the Western definition of the family differs from the African definition of the family:

> ...because when I talk in Western language..I am talking about a father, mother and child. In our (African) set up, I am talking about the grandpa, grandma, aunt, uncle, etc..all of them that are there, so that is my family.

This informant felt that this raises questions about consultation:

> So, if you consult, whom are you consulting, the person that has got a problem and the grandma and, you find that the grandma is so ignorant about matters like this

Informants suggested that the consultation difficulties were further exacerbated by the community's perception of HIV/AIDS as taboo topics.

AIDS and sexuality as taboo topics

It was suggested that the prospective participant be given the opportunity to identify who she perceived as family so that they could be consulted. She mentioned, however, that the community's difficulties with discussing sexuality and HIV/AIDS might make it difficult to discuss such topics with the community:

> ..it is just that in AIDS it goes with a loosening of morals, somewhere...It is associated with sex, and our community is never open about sex. So they are things that are not easily talked

> about. So if you say you are going to speak to young women...most of them are single people, who are not supposed to be practising sex already, so they are shy, although they are deeply involved in these things, but it is something that they cannot talk openly about

This informant admitted that the extended family has its advantages, but there are situations, such as when research into sensitive topics like AIDS is conducted, where it becomes problematic to have to consult an extended family.

The impact of exposure on the family

The newspaper exposure outlined previously also had a negative effect on the extended family. One informant indicated that some people were tested in the past and found to be HIV positive. These individuals each disclosed their HIV status and engaged in community education. It became clear, however, that the educators' lives became unpleasant as a result of the disclosure process:

> The families resented this and our families are big. There is somebody in Joburg that is not really in touch with this person that the latter (the person that tested positive) did not think would have a problem with the coming out process, but when it is found that in his home AIDS has been found, this becomes problematic

This highlighted the importance of thinking carefully about the decisions one makes:

> ..if it is something that is going to come out in the open, the family should know so that if it comes out, the family is ready...

She felt that it was particularly important that the family be informed, because an individual's family may soon be ridiculed about his or her condition and it would facilitate coping if they had been prepared beforehand.

It was also mentioned that some families may refuse to be researched and prohibit individuals' participation.

The implications of not consulting one's family

Some informants mentioned that although they felt individual decision-making should be respected, there were often subsequent problems for one's relationship with the family:

> It would depend on her. It is up to the person making a decision to decide what to do, it depends on how her family relates...sometimes you find that you make a decision on you own and you later need your family to be involved

> I must respect the fact that a person is able to make a decision about her life....but if you have not consulted your parents, and maybe a problem crops up, as an example, and you get injured or any other thing happens,...they often say among us black people: you did not tell us, so fend for yourself...

> Mmm...nothing would happen, that might stop her, but according to a black person's way of life, it is up to her to take a blessing from home...

> Then you have to respect her say...That is what we term self-determination, so leave the person like that, but...you might find that I now think that I have mastered this thing and you can now talk to my grandma and aunt that I share with...

Informants appeared to be suggesting that individualistic decision-making was permissible, but the individual could not permanently refuse to inform the family about participation in research, as this might have negative implications for the support that one might receive from the family.

Some informants felt that any lack of consultation with the family would have negative implications for one's relationship with the family:

> Maybe, in my opinion, there might be a misunderstanding and they might ask: What did she think we would do if she told us that she would be participating in research?

> That would be something that causes conflict in the family and *umndeni ungahlakazeka* (literally means becoming messy but is used to refer to the family being divided in this context) because everything must start from the agreement

> ...if she has not mentioned it, it seems as if she is stealing and if a person is working, she must work in a relaxed manner

> There would be disappointment, sadness and they might even alienate her..because if we talk about something like the research that you will be doing...it affects the lives of the people directly

A suggestion was made that the individual herself might end up being depressed from the lack of support. It was also suggested that lack of consultation exposes one to grave danger.

Most informants felt very strongly about the implications of not consulting with the family and appeared to be surprised by the suggestion that somebody could forego family consultation.

Some informants suggested, however, that there were important reasons that justified lack of consultation:

> ..because it might be that God has revealed to her...revealed to her first that I would like to work with you, because there is research that I would like to be done that will save the whole nation...her family should understand

The fact that AIDS and sexuality were topics that the community did not feel open about was also perceived as an understandable reason for not consulting one's family about participation in research.

4.6 THE ROLE OF PARTNERS

Some informants stated that it was very important to consult with partners before research participation. A few informants even suggested that the researcher should ensure that partner consultation occurs:

> ...researchers should tell her, while they inform her about research, that she should talk about it at home with her husband so that we can get into it after we have heard how your husband feels about it and how she welcomes it

Some reasons were provided for partner consultation and these are considered next.

Motivation for partner consultation

Suggestions were made that prospective participants should comply with family expectations of consultation:

> Ehh...particularly if she is married...the husband must know what she will be doing she can't just go and do something the husband must know what she is going to do

> ...there should be a good relationship between my wife and myself...because as I live with my wife we are living in peace...nobody makes own decisions and refuses to discuss with other...we in the spirit of being Christians take everything and put it in line, in good spirit

Some male informants felt very strongly about partner consultation and seemed surprised by the possibility of their wives making a decision to participate without consulting them. A few female informants also felt that a female prospective participant, irrespective of her educational status, could not make a decision without consulting her husband.

The benefits of partner consultation

The benefits of family consultation that were outlined above, such as spiritual guidance and support, blessings, and encouragement, are also applicable to partner consultation:

> If you are married, it is best you discuss this with your husband, because it would not help to research ma and find that she has nothing, without checking the father, it is better if they go and get researched together

The implications of lack of consultation:

Some informants suggested that there were various, mostly negative, implications for not consulting one's partner about participation in research:

Some informants suggested that this was likely to be perceived as lack of respect:

> You see in areas like this that are rural...that might be perceived as: that woman does not really respect her husband. Even in urban areas...as a partner in a marriage we should communicate about the things we do..the home might be affected if she does things without notifying me...as a father of the house

Some informants felt that nothing would happen if there was no consultation:

> ...these things have long been happening and you see that ohh some research has been done here, because you see that some research has been done, but what we do is sleep over it (let it pass), because you see that maybe this research is helping you

> Nothing would happen, nothing. Because there are things that people do not talk about. And because there is nothing (bad) that is going to happen...

These informants seemed to be suggesting that lack of consultation was justified if it meant that the family would benefit and remain unharmed.

A few informants felt that this would be indicative of lack of trust and sharing:

> In my opinion, that would be very problematic..I would wonder about trust and sharing...I would ask myself how one could do this despite us living together, couldn't he say?

Very few informants suggested that this would result in negative perceptions about that home:

> *Kobe kusho ukuthi isehlathini kulomuzi* (that will mean that house is a jungle, or forest)

> That will mean that is not a healthy home..they do not live well together...if they are staying together they should stay in peace and if she does not talk about this thing, then the Spirit of God does not exist in that home

4.7 THE ROLE OF THE COMMUNITY

All the informants highlighted the importance of community involvement during the informed consent process. The different dynamics of community involvement were outlined. Most of the informants suggested that informed consent was largely determined by whether prospective research participants felt that the research would benefit both the individual and the community or not. Some informants emphasised the importance of informing the leaders about potential research, while others referred to how the community had to be educated about what research entailed. The importance of community leaders is discussed first.

Motivation for informing the community leaders first:

The informants indicated that it was very important to inform the community leaders about research before its actual commencement.

> What I have seen working in rural communities is that you first have to be in touch with community leaders and win them over first with regard to what you want to do. Then it becomes possible for you to work easily with regard to what you want to do

> I often think if you want to work with them it is best to get involved with the community structures that are already established in the community

> ...if the priests could play a large role, because I think that they are able to comfort people

The informants admitted that this would not be an easy process:

> ..you'll find yourself answering the same question. Others are very tearing questions, but you have to just win them over..

> ...even though this is time consuming, but you need to take things step by step. You must win them over first, you sort of sell what you want to do to them first..then they will be convinced...

> Because if it is going to be possible to work well with the structures: amakhosi, izinduna, ...you should know that they are these type of people that need to be given their place and be respected

One informant highlighted the importance of providing feedback:

> ...maybe it would be nice to go back to those people that you approached before when you wanted to do this thing. discuss this thing with them, say what will be publicised, then you will avoid that people just get a shock when something is advertised...everybody could (then) say this is our work...as the whole community

The numerous benefits of working with the leaders as described below.

Facilitates community awareness:

> ...once you have convinced them, the chiefs will spread the gospel..so that by the time you call for a real *imbizo* (community meeting), they (people) already have it in their minds what you have come to talk about and your thing becomes acceptable

Helps prevent community conflict:

> So that you do not have a situation whereby it is said: there are people here that we do not know about, and some might say: "there are people that are messing about with us, and the chiefs don't know"...and you find that it seems as if the chief is slack and has left people to fend for themselves...

Facilitates community cooperation:

> ...people do not think a lot about why this person wants to talk to us, but because *Ndabezitha* (chief) has said they should, then they will go to this person

The importance of community education

Most informants felt that the community often did not know the researchers, and were uninformed about the purpose and potential benefits of the research:

> Ehh..it might be the truth that people are sometimes not happy. What I have observed is that this happens when people have not really been informed about what the purpose of research is and how people are going to benefit from research

Most informants suggested that because the community had limited knowledge about research and researchers, had misconceptions about research topics, and seemed to be generally unhappy about past research, there was therefore a need for large-scale community education:

> In my opinion, a lot of time should be dedicated to educating. You see time for educating so that by the time you get here people will really know. There must be nothing left behind and it must really be explained that those that we used in past research were given something, because people's legs were working...that must be something that people are given...

> I think people should again be educated about what research is. They should also be educated about what benefits they could get from research, and also the fact that they would not be affected in any way

Some informants emphasised the importance of facilitating a sense of community ownership of the project:

> ...the community must be a part of it. They must own it and it must become theirs...and respect for something that is happening in an area..that if something is brought into a community..this is here to protect us not that researchers are just playing with the things already happening in the community, but to empower them...by giving them something that will enable them to develop

> ...they are often keen on things and they love them and are eager to get involved...it thus becomes easier to get that which you wish to find...if you include them and the process becomes theirs...

Informed consent as determined by anticipated individual and community benefits

Although some informants indicated that prospective participants' informed consent was determined by anticipated individual benefits, most informants suggested that anticipated benefits for both the individual and the community would largely influence the informed consent process.

> ..the person should be told who this will help..whether this will help him or her only or whether it will help other people as well?

> They participate so that the community in which they live could be assisted and for that person herself to benefit

> If they see a need, that this will benefit, not me, but even the generation to come

> ..she, as a member of the community, will benefit when the community gains something, because she is a member of the community

There was also the perception that people participated in order to facilitate the sharing of knowledge and development:

> ...it is helping each other in the community...so that there is ukuxwaya (caution), in other words we warn each other

> It might have to do with the fact that you wish to work for the nation. It might also be that if there is something happening in the nation that we do not know about, you might then wish to be a part of that so that you might be able to spread knowledge

> It is running away from anger...it is like here in Hlabisa, we do not have enough potential of making a living for ourselves. Making a living for ourselves is to have firms so that we do not go to Joburg, Durban, Richard's Bay and then end up getting into trouble

This suggests that the African person is not generally perceived as separate from the community, but as part of the community benefits and losses.

Conclusion

The aim of this chapter has been to explore the main themes that emerged from the study. An attempt has been made to illustrate key informants' perceptions about Hlabisa people's conceptions of research. It has been shown, for example, that although some people are ignorant about research, some are likely to perceive it either as an information-gathering, problem-solving, and/or educative processes. Informants suggested that although there had been some benefits from past research, people's experiences with research appeared to have been largely negative. Suggestions were made for rectifying the situation.

Informants' conceptions of informed consent were also presented. Most informants emphasised the importance of establishing a relationship between the researcher and prospective research participants. This would entail the disclosure of information about the research project, and respect for the participants. The informed consent process was mostly described as a process that should involve the research participants' partners, families, and the community as this was likely to prove beneficial. Some informants indicated, however, that the level of consultation practised should be determined by the individual's preferences. This was described as unlikely to be a permanent arrangement, however, as the prospective research participant was likely to need support later on. The main themes and the sub-themes are interpreted further in the next chapter.

5. DISCUSSION

The aim of this chapter is to interpret the results presented in the previous chapter. The components of informed consent will be explored first, with particular attention to the multi-level relationships that exist within this process. The role of families and community leaders which has been identified as important when working with socially embedded individuals, will be considered next. Multi-level relationships within the research setting are likely to have power differentials, and these are also discussed. An attempt is then made to explore what the theoretical implications of the study are.

5.1 COMPONENTS OF INFORMED CONSENT

Information

Informed consent has been described as a process whereby prospective participants give consent to participate in a research study after they have been informed about its general nature (Locke et al, 1993). There are indications that the transmission of information should be designed to enable participants to understand what the implications of research participation will be, an area which has been considered to a relatively limited degree within the informed consent literature.

Traditionally, the informed consent process has involved the unilateral transmission of information by the researchers, who are supposed to be experts, to prospective participants (Meisel & Kuczewski, 1996). There are indications that there is a need for a shift from unilateral transmission of information towards a bilateral transmission of information, particularly when researchers and participants come from different cultural backgrounds.

This would involve a mutual exploration of the cultural beliefs that both the researchers and participants bring to their encounter, as these may impact on research participation. Researchers may have to be informed about participants' cultural beliefs as these may impact on the research study (Gostin, 1995). Informants suggested, for example that there is a belief, among some Hlabisa people, that HIV/AIDS is caused by bewitchment. Beliefs such as these are likely to impact on research participation.

Prospective participants from an area like Hlabisa may, partly as a result of the eco-socio-political context of their area, have expectations about research participation. The informed consent process is likely to be enhanced by a mutual exchange of information about the goals, expectations, experiences, and fears. This is likely to facilitate the shared decision-making that has been described as likely to accommodate the interests of the researchers and the participants (Meisel & Kuczewski, 1996).

Meisel and Kuczewski challenge what they term "the standard rendition of informed consent" (1996, p.2522), whereby there is a unilateral transmission of information from the researcher to the prospective participant. The participant's role in this scenario is to consider this information in the context of their values and then choose the course of action perceived as suitable to themselves. Meisel and Kuczewski recommend instead that informed consent be approached as a shared decision-making process, which would involve a mutual exchange of information. The researcher would provide relevant information about the study, and the prospective participant would also inform the researcher about personal and cultural values that might impact on participation.

The participant might also ask for more time to think about the information provided and seek the physician's opinions with regard to what she or he thinks should be done. Meisel and Kuczewski suggest that this approach ensures that information transmission is not entirely left to the researcher but ensures that the participant is involved. The values of both the participant and the researcher would then be accommodated.

Traditionally, the informed consent process has also entailed information transmission to the prospective participant only, in line with Western emphasis on respect for the autonomy of the individual. The current study suggests that researchers may have to shift the exclusive focus on the individual to include the family and/or the community, particularly in societies such as those in Africa, where the social-embeddedness of the individual is emphasised (Christakis, 1988; Gostin, 1995). All the informants indicated that prospective research participants exist within a social context whereby significant others such as partners, parents, and the community may wish to be informed about the general nature of the research study. This suggests that researchers intending to work in collectivistic cultures may have to consider multi-level transmission of information.

Information transmission to families and communities might prove time-consuming and challenging. More clarity with regard to actual implementation seems warranted. Several authors have recommended working with individuals who represent the local community that is being researched, particularly when there is reason to believe that the prospective participants have different cultural beliefs from those of the researcher. The formation of such community advisory boards would enable the researcher to learn about the society that is about to be researched (Barry, 1992; Bayer, Levine, Murray, 1984; Gostin, 1995; Levine, 1991; Valdiserri, Tama, & Ho, 1988).

Gostin (1995) recommends, for example, that the board should include people who have experience and understanding of prospective participants' culture, customs and language, in order to ensure that the researchers have the opportunity to learn about participants' ways of life. This could provide a forum for researchers, participants, families, and communities to engage in meaningful dialogue about various expectations, thus ensuring a thoughtful and respectful decision-making process. This is likely to increase cultural sensitivity and reduce the potential for legal liability.

Barry (1992) suggests that such boards should involve people who are uninfluenced by the prospect of money, prestige, or personal gain from the project, whose role would be to provide an ongoing evaluation of the project in order to contribute towards its success. Community advisory boards would also provide a forum for the discussion of issues that arise from the research investigation, such as confidentiality guidelines, and volunteer recruitment techniques. The advisory board might serve as a communication link with the researched community (Valdiserri et al, 1988).

Researchers might also explore, with the advisory boards, what would be the most culturally appropriate approach for handling discussions on sexuality and HIV/AIDS, which are often perceived as taboo to talk about. Community advisory boards are therefore likely to facilitate an exploration of the multilevel expectations of the participant, researchers, family, and community. The boards cannot, however, be regarded as substitutes for the important relationship that should be formed between researchers and participants.

The importance of community advisory boards is not limited to cross-cultural research. Such boards would also be beneficial in research settings where researchers and participants share

cultural characteristics. Advisory boards become particularly pertinent, however, in cross-cultural settings. There appears, to be a need, however, for further research on the dynamics of the relationships between community advisory boards and researchers.

Understanding

Prospective participants might find it more challenging to understand the information transmitted during cross-cultural research, particularly if they have had limited exposure to research. The situation is likely to be exacerbated when the participants are second- or possibly even third-language speakers of the researchers' language. This does not suggest that it would be impossible to attain participants' understanding (Adityanjee, 1986; Angell, 1992; Ijsselmuiden & Faden, 1992).

Challenges to understanding the scientific methods of trials are, however, not limited to the African context (Snowdon, Garcia, & Elbourne, 1997). Empirical studies suggest that participants often do not understand major portions of that to which they have consented (Silva & Sorrell, 1984). However, comprehension difficulties are likely to be exacerbated in cross-cultural research, particularly if extra care is not taken to ensure that there is adequate understanding of the research process.

Researchers might benefit from soliciting the assistance of the community advisory boards described above. Technical terms such as "randomized" could be discussed with the board since they are much more knowledgeable about the community and the type of language that is commonly used (Bayer et al, 1984). This might facilitate a process whereby information is presented in culturally relevant terms in order to facilitate understanding (Barry, 1992; Christakis, 1988; Preziosi et al, 1997).

There are indications that researchers might have to give participants more time to consider the information provided, and share it with family members (Adityanjee, 1986). Although continuous discussions between researchers and prospective participants are important in every research setting, this is particularly important in a cross-cultural setting. Relevant information that is conducive for understanding and relationship-building would be given in order to ensure that the informed consent process involves shared decision-making (Meisel & Kuczewski, 1996).

Researchers need to ensure that prospective participants have heard well and are not of the perception that they were tricked into making decisions that they would not have made, had they fully understood the implications of research participation. Researchers have to ascertain that participation in research is not construed as exposure to harmful situations for participants, but as beneficial for researchers, as this might perpetuate the belief that research is exploitative (Del Rio et al, 1997).

Various interventions need to be considered to facilitate participants' understanding. The use of pre-recorded video-tapes for the transmission of information in a manner that would be accessible for the community to be researched might prove useful in facilitating conversation and understanding (Roth et al, 1982). Non-participants, such as those that sit on the community advisory board might also be asked to critique drafts of informed consent documents for accessibility (Morrow, Bennett, & Carpenter, 1983).

The use of anticipatory questions during the information transmission phase, such as asking a prospective participant what might transpire should she or he have a positive HIV test result, might also prove useful. Such questions could broaden understanding of the implications of participation and initiate the mobilisation of social support for the prospective participant should this be required at a later stage (Stevens & Doerr, 1997).

There are indications that it is essential that the researchers understand prospective participants' life circumstances, cultural beliefs and contexts as these may have an impact on participation in the research study. The concept of understanding as a bilateral process has, however, been seldom explored in the literature. The informed consent process is often presented as the unilateral transmission of information from the researcher to the prospective participant, who is then expected to passively consent to participation (Veatch, 1995).

The researcher is seldom presented as someone who might benefit from understanding participants' life circumstances. Researchers frequently have very limited understanding of the research participants, and are thus more likely to conduct the research in a manner that is guided by their own beliefs and preconceptions. Participants' values might be undermined in the process and shared decision-making difficult to achieve (Meisel & Kuczewski, 1996). A culturally sensitive approach that involves the willingness to learn from research participants,

their families, and their representatives might enhance researcher understanding of the study dynamics.

Hlabisa, like most collective societies in the developing world, appears to emphasise the social embeddedness of the individual. Researchers' exploration of how the community might interpret participants' role in the research study is probably warranted, particularly in small villages where confidentiality might prove difficult to ensure (Barry, 1992). The implications of research participation for the whole research community might also have to explored.

Consultation might facilitate better understanding of the economic context of the researched community, and how this impacts on research participation. It might also enable better understanding of the cultural context of the researched community, for example, the beliefs that people have about HIV infection. Researchers might also gain insight into the social context, for example, the nature and impact of extended families. Researchers' understanding of the eco-socio-political context of researched communities would also facilitate greater awareness of the power differentials that exist between researchers and the communities in which they work.

Motivation

Mutual exploration of expectations might alleviate misunderstanding and facilitate researcher insight into life circumstances that might make prospective research participants vulnerable to inducements. Prospective participants might be more likely to participate if they anticipate health benefits. This confirms the suggestions made in the literature that participants from developing countries tend to participate under the mistaken notion that they are being treated (Adityanjee,1986; Christakis, 1988). It has been indicated, however, that this mistaken notion is not limited to the developing world only (Appelbaum, Roth, Lidz, Benson, & Winslade, 1987).

Anticipated economic benefits are likely to motivate prospective participants to give their consent to participate. Such expectations need to be explored and a realistic statement of the anticipated benefits might have to be provided. This is discussed further under the voluntariness component.

Prospective participants might give their consent to participate in research if they feel that they might acquire knowledge about, for example, health issues and referral sources, which suggests that there is an underlying assumption about the benefits of allopathic medicine (Adityanjee, 1986). This poses a challenge for researchers to ensure that the prospective participants fully understand what the implications of research are.

Participants might participate because they are willing to sacrifice their personal interests for others to be helped, and this is perceived as indicative of maturity in their communities. This confirms the suggestions made that people from predominantly collectivist societies tend to sacrifice personal interests for collective interests, and to give priority to sharing resources with group members and group resources (Ikuenobe, 1998; Matsumoto, 1996; Triandis, 1994).

Most of the informants indicated that prospective research participants would be more willing to consent to participate in a research study if they felt that the study would also bring about benefits for their community. Individual benefits may not be so relevant in societies that emphasise the sacrifice of individual goals and benefits for the benefit of the society (Markus & Kitayama, 1994; Matsumoto, 1996; Triandis, 1994).

Researchers might therefore have to reconsider the benefits of a research study conducted in collectivist societies. This highlights the importance of advisory boards where information about benefits would be shared and discussed. There indications that there has been limited consideration of prospective participants' expectations and this warrants further investigation.

Voluntariness

The ability to make choices without influence from others or coercion is one of the essential features of the informed consent process. The concept of uncoerced choices may, however, contradict cultural beliefs that emphasise obedience to the wishes of family elders and partners (Gostin, 1995). Suggestions have been made that significant others such as community leaders, family, and partners be approached for permission to approach the prospective participants.

A few informants suggested that some families may strongly object to members' participation in research, and this may make it very difficult for the prospective recruits to consider

participation. This raises concerns about who to obtain consent from. It is also indicative of the need for the researchers, participants and the community advisory boards to constantly reconsider how to deal with such dilemmas as they impact on the informed consent process. This respect for the role and influence of relevant others cannot, however, be a substitute for individual consent (Ijsselmuiden & Faden, 1992; Olivier, 1995).

The concept of voluntariness becomes particularly complex in a social context within which human beings are not necessarily granted equality, but are positioned uniquely within the community according to age, gender, kinship, wealth, character, and much more (Verhoef & Michel, 1997). It is likely that the hypothetical young female used as an example for the purposes of the study, has less freedom of choice than some others and is expected to obey the commands of elders. A young single woman might have to inform her parents about prospective participation, as young people tend to remain children in their parents' eyes. This poses a challenge for researchers to ensure that they pay attention to the power dynamics that exist in participants' social contexts. It is also possible, however, that parental influence might be diminishing as a result of acculturation (Georgas, 1989; 1991).

Prospective participants may expect economic benefits such as payment for participation, possible employment by the researchers, and the provision of food; all of these are likely to encourage participation. Such expectations result from the poor economic situation in which participants in poor communities find themselves. Benefits for participation may unconsciously or deliberately act as inducements and make people vulnerable to coercion (Adityanjee, 1986).

Benefits should not be so large that they induce prospective participants to consent to participation against their better judgement. It may be difficult, however, to distinguish between suitable recompense and undue influence to participate in research (CIOMS & WHO, 1993). An unemployed person may view compensations differently from an employed person. Similarly, a person without access to medical care may be unduly influenced to participate in research, solely to receive such care. Suggestions have been made that researchers bear this in mind and proceed with caution when dealing with people from developing countries who may be particularly vulnerable to inducements because of their economic situation

Researchers might have to consider sharing ideas with the community advisory board about what constitutes fair compensation for participation. Because community advisory board members are generally well-informed about transport costs and the needs of the community, they might be in a better position to make recommendations about what constitutes fair compensation.

Voluntariness refers to prospective participants' awareness that they have the freedom to withdraw their participation when they find it impossible to continue their involvement in a study. Participants need to be informed that their withdrawal would not discriminate against them (Locke et al, 1995). The research setting is, however, fraught with power imbalances, as will be discussed below. Some participants believe that they are not allowed to withdraw from studies, and that withdrawal might result in the loss of medical care. They might then continue to participate when they no longer wish to, and this defeats the purpose of voluntary informed consent (Abdool Karim et al, 1998).

There appears to be a challenge for researchers to establish a relationship with prospective participants as this might facilitate a process whereby participants are asked at various stages what their experiences of research participation are, in order to ensure that concerns are addressed. This might also make it possible for participants to be constantly reminded about the voluntary nature of participation, thus ensuring that they are aware that they may withdraw anytime without negative repercussions. An ongoing informed consent process is therefore warranted.

Consent

Prospective participants are required to make a decision about whether or not to participate after they have been given information about the general nature of the research investigation. Researchers often make the assumption that prospective participants are able to make autonomous decisions with regard to research participation (Barry, 1992; Christakis, 1988; Gostin, 1995). There are indications, however, that collectivist societies, such as Hlabisa, tend to perceive decision-making as a consultative process, which should include partners, families, and the community (Markus & Kitayama, 1994; Matsumoto, 1996; Schwartz, 1990; Triandis, 1994).

The researcher might have to extend the solicitation of consent from the individual to include significant others such as the participants' partners, family, and community (Christakis, 1922; Gostin, 1995), should the participant indicate a preference for this to occur. More time might have to be allocated to holding meetings with participants' immediate families in order to facilitate decision-making about whether to give consent for participation or not.

It has been suggested, however, that collaboration with family members and community leaders cannot be a substitute for the participants' individual consent or withdrawal thereof (Ijsselmuiden & Faden, 1992; Olivier, 1995). Respect for participants' interests is likely to facilitate shared decision-making and ensure that the participants feel that their needs are taken into consideration (Meisel & Kuczewski, 1996).

Although most informants felt that an individual should consult about possible research participation, some indicated that an individual could make individual decisions without consultation if it was felt that this would not harm the collective. It was felt, however, that individual decision-making could not be permanent as the participant was likely to need the support of her family at a later stage. Respect for the individual should accommodate the wishes of a participant that does not wish to include her family. Support structures might have to be introduced should such participants require them.

Consent to participate in a research study could be given orally and by signing an informed consent form. The signing of informed consent forms might, however, be complicated by the socio-political context of the researched communities. Hlabisa, like most communities societies in the developing world has high illiteracy levels (S.P.A. consultants, 1994). Most people would therefore have difficulties reading and comprehending the forms.

The situation is exacerbated when participants are second-language speakers of the language spoken by the researchers. Informed consent forms might therefore have to be translated into the research participants' home language. Collaboration with community advisory boards during the translation of the document may prove helpful in ensuring that the informed consent form is accessible to prospective participants (Bayer et al, 1984).

Researchers might have to consider combining oral and written information in order to achieve a better quality of informed consent (Kerrigan et al, 1993). Informed consent forms

should be primarily geared towards protection of the participants and not the indemnity for the researchers only. This is particularly important if the conduct of past research has resulted in suspicions about researchers' motives.

5.2 MULTI-LEVEL RELATIONSHIPS IN THE RESEARCH SETTING

Most informants highlighted the importance of establishing a relationship between researchers and research participants, particularly during the informed consent phase. The informed consent process consists of multi-level relationships between researchers, the research participants, participants' families, and the community. These multi-level relationships are considered in this section.

The researcher-participant relationship

The importance of establishing a relationship between researchers and research participants has been referred to in the section on components of informed consent. Although this would be essential in every context, it becomes particularly pertinent when there are cultural differences between researchers and participants. A good working relationship between researchers and participants is likely to provide a forum where various issues such as participants' conceptions of research, and their cultural beliefs may be explored. Relationship-building is particularly important in societies that emphasise relatedness. These issues are considered below.

a) Participants' conceptions of research

There are indications that an exploration of participants' understanding of research is particularly important when there are indications that people have a limited understanding of what research entails (Adityanjee, 1986; Christakis, 1988). This exploration might facilitate a better understanding of motivations for participation, and provide a forum where both researchers and participants mutually explore what research has to offer. This process should ideally involve community education and clarification with regard to the limitations of research.

b) Past experiences with research

All the key informants emphasised the importance of establishing a relationship between researchers and research participants. This is particularly essential in an area like Hlabisa that has reportedly had negative experiences with past research. There are indications that people

had wanted to establish good relationships with researchers. Some had even thought that they were equal partners with researchers. People would have appreciated some information as this would have facilitated a sense of ownership of research projects. There had, however, been a lack of information about research conducted. There was also a perceived lack of preparation for the implications of research. People's expectations of research were neither explored nor met.

This suggests that the conduct of research is likely to be construed as an expression of a relationship by participants. Research relationships have, like most relationships that people form, obligations to be met. Whether these obligations are met or not has implications for how researchers are perceived by participants.

Whereas people had wanted to build a relationship with researchers, they received what they experienced as negative media exposure, which has had negative far-reaching implications for the community. Exposure appears to have resulted in fear of researchers' ulterior motives and the impression that research is exploitative. This is indicative of the need for researchers to exercise caution when conducting research as research might have economic, social, and political ramifications (Barry, 1992). It also confirms Stark's (1998) suggestion that research is a social endeavour that occurs within a context in which researchers and participants are embedded. The conduct of research is therefore likely to have far-reaching implications for the individuals, families, and communities that exist within the social context (ibid).

People appear to have formed the impression that research has benefits for researchers only, and not for the community. This perceived infringement of the basic principle of justice may make it difficult to establish future trusting relationships with participants (Del Rio et al, 1997). Shared decision-making, which is essential for the informed consent process, might also be negatively affected.

There are indications that researchers may benefit form establishing a relationship with research participants. Participants from predominantly collectivist societies, such as Hlabisa, tend to emphasize the importance of relationships, thus confirming the suggestions made that this is due to being socialised to view the world in terms of relationships. The maintenance of good relationships with others is perceived as moral behaviour (Verhoef & Michel, 1997).

Researchers and prospective participants might benefit from a mutual exploration of expectations with regard to the researcher-participant relationship. It might, however, prove challenging to encourage participants to be forthright about their expectations and motivation for participation in research, as a result of the power dynamics that often exist between researchers and participants. Both the researchers and participants might learn more about each other as the relationships between them improve.

Researchers might learn, for example, that participants expect an open, friendly, and honest approach. Participants might also learn about researchers' expectations of them as research participants. Community advisory boards might prove informative with regard to what facilitates good working relationships with participants. Researchers might, for example, be invited to play a directive role and communicate with participants' families on behalf of participants. The community advisory board could prove useful with regard to how to do this.

c) Respect for cultural differences

Most informants suggested that respect for participants' cultural beliefs would facilitate the establishment of relationships between researchers and participants. It has been suggested that an attempt to obtain the consent of participants in a manner that is consistent with participants' cultural values, is indicative of respect for human dignity, which is necessary for good working relationships to be established (Gostin, 1995). Researchers might have to explore what the cultural beliefs of the participants are, particularly with regard to research and the research topic.

It has been suggested that although understanding might prove more challenging to achieve in cross-cultural settings, it is nonetheless achievable. Prospective participants are likely to benefit from being educated about the research topic in a manner that takes existing cultural beliefs into consideration (Adityanjee, 1986; Angell, 1992; Barry, 1992; Christakis, 1988; 1992; Kempf, 1995). Researchers have to ensure that participants feel they are listened to and respected, and also educated about cultural beliefs relevant to the HIV/AIDS epidemic. Members of the community advisory board, who have experience and understanding of the participants' culture, customs, and language, may prove helpful in this regard (Gostin, 1995).

Establishing a relationship of confidence between researchers and participants is necessary for the informed consent process. This would facilitate a process whereby both the researchers

and the participants are able to continuously explore the implications of the information provided in order to ensure that shared decision-making is obtained (Meisel &. Kuczewski, 1996). Such emphasis on shared decision-making is likely to accommodate the protection of both the researchers and participants.

Relationship with families

Individuals from collectivist societies such as Hlabisa, tend to have an interdependent construal of the self (Matsumoto, 1996; Triandis, 1994). It has been suggested that researchers should solicit consent in a manner that demonstrates respect for participants' cultural context (Gostin, 1995). Good relationships with participants' families should be established, particularly if participants indicate a desire for their families to be involved in the consent process.

This is particularly pertinent in societies that regard failure to consult families as a moral transgression (Verhoef & Michel, 1997). The family support and guidance received by a participant that has consulted them may facilitate better progress within the researcher-participant relationship, as the participant is unlikely to be consumed by guilt and regret that might result if she has not involved her family.

Collectivistic families are, however, characterised by extended primary groups (Schwartz, 1990). This raises questions about who to consult and who is family. Answers to such questions are likely to be determined by the changes that each family has experienced. The establishment of a good relationship between researchers and participants is necessary to ensure that there is a mutual exchange of information about expectations and preferences with regard to family consultation.

Some authors (Christakis, 1988; 1992; Gostin, 1995) call for family consultation, particularly if the participants have indicated a preference for this. Other authors have indicated, however, that this should not be a substitute for individual informed consent (Adityanjee, 1986; Angell, 1992; Barry, 1992; Benatar, 1998; Ijsselmuiden & Faden, 1992), particularly because individual differences were observed in this study.

Some informants suggested that family consultation depends on individual preferences and the nature of the family. Some participants might regard individual decision-making as

perfectly acceptable, provided a realistic assessment of the implications of participation has been made. Informants' perception that such individual decisions could not be permanent bears testimony to the importance that individuals from collectivistic societies attribute to relatedness.

Possible preference for individual decision-making confirms the suggestions made that cultures are not static, but have changed as a result of external and internal influences such as Westernization, civil warfare, migrant labour, and much more (Berry, 1995; Georgas, 1991; Ijsselmuiden & Faden, 1992). This poses a challenge for researchers to ensure that research is conducted in a manner that acknowledges cultural changes.

A few informants indicated that some families may forbid participation in research. Families might be more controlling when research participation involves a young single female. This raises concerns about who should be informed and who should give consent for participation? This also challenges researchers to learn about the power dynamics that exist between participants and their families.

While some informants recommended a family-oriented decision-making process, others supported an individual process. Such differences reflect the ongoing debate between scholars that recommend the solicitation of individual informed consent and those that encourage the involvement of families and community leaders.

This study suggests that family involvement in the informed consent process seems essential for collectivist societies. This may not, however, be regarded as a substitute for individual preferences, particularly because there are expressed differences about the involvement of families. This is suggestive of a need for researchers to be guided by participants' preferences. Some participants might request family involvement from the beginning, others may seek later involvement, while some may choose to make all decisions on their own. The informed consent process is likely to be enhanced by a process that ensures that participants are respected.

Relationship with the community

The importance of establishing a good working relationship with the community was emphasized by the informants. The conduct of research in collectivist societies that place

emphasis on respect for authority (Schwartz, 1990), should be preceded by gaining the support of community leaders. This could be achieved by establishing with community leaders and seeking their permission for research to be conducted in their area of jurisdiction.

This is best done in a manner that facilitates good relationship building. This would involve working with leaders in a manner that demonstrates respect for them in their areas, by ensuring that they are informed about research before it begins. Researchers should therefore make appointments to meet with leaders and inform them about the general nature of the study, including information about its purpose, duration, benefits, and risks. This information would have to be presented in a manner that facilitates understanding of the scientific issues and the implications for research participation.

Researchers have to be prepared to answer numerous questions about why a particular community has been chosen for research, and what may be expected from participation. Members of the advisory board might prove useful in terms of informing researchers about the culturally appropriate methods of working with community leaders.

As Stark (1998) suggests, research involves not only the individuals whose consent to participate is sought, but also the identifiable groups to which they belong. He adds that it is a matter of common courtesy and ethical best interest to request consent from the leaders of target communities prior to conducting research with members of the community, as failure to consult may contribute to the perception that research is conducted by "experts" on people rather than with them, and may further disadvantage people who are already disadvantaged.

Researchers will have to inform leaders about how the information obtained from the study will be handled, including whether leaders will be given feedback, and whether results will be published in media or not. Stark asserts that researchers have an ethical obligation to communicate their findings in a manner that can be understood by the people that assisted them by participating in the research.

The consultation of leaders may result in numerous benefits for researchers. Some informants mentioned, for example, that Hlabisa's traditional leaders command considerable respect among their subjects. They might mobilise support for the research study if they have been properly informed about it, and are convinced that community participation will be

beneficial. Community members tend to co-operate with what their leaders have recommended, because they believe that their leaders are unlikely to recommend what may be detrimental for their subjects. As Christakis (1988), such respect for leaders should not be abused to the detriment of the prospective participants.

Most informants recommended obtaining the permission of leaders for research to be conducted in their areas of jurisdiction. There was very limited support for the solicitation of leaders' proxy consent for their subjects. Such limited support for proxy consent is also reflected in literature, and is indicative of acculturation as a result of, for example, Westernization, the migrant labour economy, warfare, and much more (Ijsselmuiden & Faden, 1992; Olivier, 1995). This poses a challenge for researchers to ensure that they remain sensitive to the cultural changes that occur in participants' contexts. Community consultation with participants themselves, and members o the community advisory board may help in this regard.

Several authors have reported that proxy consent is fraught with difficulties, such as the possible susceptibility of leaders to inducements which may defeat the purpose of informed consent (Adityanjee, 1986; Angell, 1992; Barry, 1992; Benatar, 1992; Ijsselmuiden & Faden, 1992). Participants may also be reluctant to refuse to give their consent to participate out of fear to incur the wrath of leaders who have recommended participation.

There is a challenge for researchers to ensure that they understand the power differentials that exist between research participants and their leaders. This is particularly important when the research involves groups with particular gender and age characteristics. Leaders' responses are likely to be more controlling when asked about a young female subject's participation in research, than they would be if they were asked about an older man (Verhoef & Michel, 1997). Proxy consent is therefore far from ideal and may perpetuate gender and power differentials, with implications for the voluntary nature of informed consent. Extra caution should be exercised when participants indicate prefer proxy consent, in order to ensure that their participation remains truly informed and voluntary.

Collaboration with leaders is likely to be perceived as indicative of a culturally sensitive approach. This should not, however, be regarded as a substitute for participants' preferences. Participants, particularly those from collectivistic, traditional communities, may have to be

constantly reminded that they may withdraw at any time, in spite of their leaders' support for the study.

5.3 POWER DIFFERENTIALS

The research setting is characterised by large power differentials between researchers and participants, possibly because of the often better economic, social, and educational status of researchers compared to that of the participants. Power differentials may also exist as a result of the political history of the country in which the research is conducted. South Africa, for example, had apartheid policies which were designed to make African people believe that they are inferior to White South Africans. This may have an impact on the research setting in which most researchers are White, while participants are often African (Christakis, 1988).

The unequal relationships that exist between researchers and participants are, however, not limited to the African context, but have also been documented in the Western context (Gordon & Paci, 1997). The attempts of some of the key informants of this study to create a favourable impression on the young African researcher suggest that race and gender are sometimes not the main reasons for the power differentials that exist in a research setting.

This suggests that there might be some status attached to being a researcher, which might be related to educational level and social position. The social desirability responses that the informants gave, irrespective of their powerful positions in their community, bear testimony to the effects of power differentials in the research setting.

The effects of social hierarchy on the research process have been researched to a relatively limited degree, and warrant further research. This is particularly pertinent for contexts in which participants are embedded in their social contexts, and are thus more likely to recommend family involvement, and possibly leader involvement, during the informed consent process. Families and leaders might, irrespective of their age, experience, and social standing, also provide social desirability responses to researchers in a bid to gain favour, and create favourable impressions.

Participants who participate in a research setting in which there are power differentials are likely to give responses that they believe are what the researcher would like to hear rather than what they, as participants, believe in. They might be reluctant, for example, to indicate that

they would like more information in order to facilitate understanding. They might not question the researcher on the general nature of the investigation, possibly out of a reluctance to appear either uninformed or confrontational. Participants might then agree to participate in research without having obtained the full understanding that is necessary for consent to be truly informed. This is likely to be prevalent in African settings where, as Christakis suggests, participants have a relatively limited understanding of research (1988).

This challenges researchers to ensure that prospective participants have heard well what the research study involves and what the implications of participation may be. Researchers have to ensure that they are constantly aware of the power dynamics that exist in the research setting.

There are indications that participants might participate because they believe they should participate, and do not really have a choice (Abdool Karim et al, 1998). Participants might also agree to participate, not because they would really like to participate in research, but because they believe that they are helping researchers, and are therefore likely to please researchers, and thus create a favourable impression about themselves. They are unlikely to question anything that the researcher suggests. Such participation cannot be termed truly voluntary.

Participants might be reluctant to indicate that they would like to withdraw their participation from research even when they have reached a state when they find it impossible to continue. They might believe that non-participation would compromise the quality of care they have been receiving prior to the proposed participation. This is more likely to occur when researchers are also responsible for the provision of health care to participants.

Abdool Karim et al state that this is indicative of the need for researchers to exercise caution when working with poor people who have few alternatives. Participants might have to be reminded at all times that non-participation will not compromise the care provided. Members of the community advisory board might prove useful in this regard, since their suggestions, as non-researchers, might be more convincing for the participants.

Conclusion

The components of informed consent have been discussed. Reconsideration of the informed consent process, as has been traditionally been practised, seems necessary; particularly when cross-cultural research is conducted. There are indications that the informed consent process might be enhanced by a bilateral approach towards information transmission, whereby both researchers and participants share pertinent information about expectations and goals with regard to research. The importance of a bilateral approach also applies to understanding. Although it is crucial that prospective participants understand the information transmitted, researchers should also understand participants' social contexts, as these might impact on the informed consent process.

Motivation for participation should be constantly explored, particularly when working with poorly resourced communities, as this has implications for the voluntary nature of research participation. Increased understanding of participants' eco-socio-political context would facilitate sensitivity with regard to research benefits. Researchers have to be honest about what research has to offer, and take care that their explanations do not induce research participation.

Consent is affected by the multi-level relationships that exist within the research setting. It is therefore not limited to the researcher-participant relationship, but is enhanced by an acknowledgement of participants' social embeddedness. The majority of the informants felt that the informed consent process should not proceed without the involvement of participants' families and community leaders. There was no support, however, for proxy consent from family members and leaders on behalf of participants. There were also some calls for an approach that recognised the fact that individuals could make individual decisions about participation. This suggests that cultures are not static, and may not be treated as such, particularly during the informed consent process.

The above-mentioned findings have implications for whether ethical principles, such as the autonomy of the individual, should be universally applied, or treated as relative to the cultural context in which they are applied. Informed consent procedures are likely to be enhanced by an approach that acknowledges individual autonomy and also accommodates various cultural preferences that may be expressed by the participants, such as the need for family involvement.

The power differentials that exist within a research setting are often overlooked (Goldberger and Veroff, 1995). Social desirability responses are likely to be a major feature of cross-cultural research as it often includes power imbalances between researchers and participants. The eco-socio-political context within which research occurs, is likely to make it hard for participants to express their expectations, goals, and concerns honestly. This might impact on information transmission, understanding, motivation, voluntariness, and actual consent.

It is therefore important to establish good relationships between researchers and participants. This may be enhanced by a mutual respect for cultural norms. Genuine respect for participants' wishes, whether they are communitarian or individualistic, might ensure greater co-operation. Collaboration with community advisory boards is likely to prove beneficial when there are indications that the researchers and the participants have different worldviews.

6. CONCLUSION

The results of this study confirm the suggestions made in the literature that research is a social endeavour, and this is considered first. An attempt is then made to evaluate the study's attempts to address the cultural conceptions of research and informed consent. This is followed by a critique of the theoretical foundation of the study and the method used.

6.1 RESEARCH AS A SOCIAL ENDEAVOUR

The results of this study confirm Stark's (1998) assertions that research is a social endeavour, as it is conducted among people who are embedded in a number of social contexts, each of which has social norms and cultural expectations. Informed consent, which is an essential component of research participation, should be perceived as an expression of a contract between science and society (Richter, Lindegger, Abdool Karim, & Gasa, 1999).

Informed consent cannot be described in isolation from ethics in general (ibid). Ethical research relationships require an awareness of, and sensitivity to the social, psychological, biological, and cultural contexts in which both the researchers and research participants are embedded (Stark, 1998). For example, there are always social consequences to participation in research, which occur at a personal level, as well as at a broader level that includes the family, and the community of the research participants.

The current study highlights that importance of building relationships between researchers and participants. This provides a forum for the mutual exchange of pertinent information about cultural beliefs, norms, and social expectations, as these have an impact on research participation in general, and informed consent specifically. A shift from a unilateral approach to a bilateral approach during informed consent is recommended.

An approach that perceives cultural values as homogenous and static is likely to prove counterproductive as there are substantial differences within cultural groups. Cultural values also evolve over time due to various external and internal influences. A researcher might not always get the desired information from research participants and consultation with community members is important and indicative of a culturally sensitive approach.

Good relationship-building is also enhanced by an awareness of, and sensitivity to issues relating to power and the vulnerability of prospective participants (Stark, 1998). This is particularly important in the conduct of research with poor communities that might, because of the eco-socio-political context, be particularly vulnerable to power dynamics. There are indications that participants' informed consent should be ongoing, particularly in cross-cultural research, to ensure that participants are constantly reminded of the voluntary nature of participation (Abdool Karim, et al, 1998).

6.2 A CRITIQUE OF THE STUDY

The strengths and weaknesses of the current study are presented in the following section.

An exploration of cultural conceptions of research and informed consent

The exploratory nature of the study facilitated the generation of ideas and the development of tentative theories about conceptions of research and informed consent. The results of the study indicate that participants' cultural beliefs are likely to have an impact on the informed consent process. The expressed individual differences about individual or community-oriented consent are indicative of cultural changes that may have resulted from Westernization, the migrant labour economy, civil warfare, and the HIV/AIDS epidemic.

Such differences reflect the ongoing debate on the universalistic or relativistic application of ethical principles. The individual differences observed also bear testimony to the need for individual differences to be respected, even when working with collectivistic societies. Further research on how the universalistic and relativistic approaches can be integrated is necessary.

The theoretical foundation of the study

Faden and Beauchamp's (1986) moral theory was provided as a foundation for informed consent. The framework of African morality that was presented earlier did not arise in respect of informed consent, but refers to African morality in general. Although attempts were made to illustrate how the different conceptions of personhood held in Western and non-Western contexts may impact on informed consent, a theory of informed consent that accommodates cross-cultural differences should be developed. Ijsselmuiden and Faden's recommendations that there be collaboration towards developing ethics for the South African context should be taken further (1992).

Sample size

Key informants' responses were informative about cultural conceptions of research and informed consent. The information provided cannot, however, be presumed to be representative of Africans' conceptions of research and informed consent, for various reasons. A sample of twenty three informants is limited for making generalizations. The sample was also very specific to the Hlabisa community. It therefore cannot be assumed that people from other communities, with possibly different circumstances, hold similar beliefs. Broader cross-cultural research into conceptions of research and informed consent is likely to be more informative and representative.

Understanding of informed consent

Informants appeared to have a functional understanding of informed consent. They are, however, leaders with tremendous experience, and are likely to have a better understanding of informed consent than an ordinary member of Hlabisa might have. The informants themselves indicated that most Hlabisa people have limited understanding of research and informed consent, and their rights and obligations as research participants. This is indicative of a need for more research into people's understanding of research and informed consent, as this might inform community education about research in general.

The interview guide

The guide facilitated informants' disclosure of their conceptions of research and informed consent. Although it is likely that the guide was biased in favour of the better educated informants, poor comprehension was not a major feature of research participation. The researcher's employment by the organization that had conducted the past research that most people were unhappy about, is likely to have resulted in socially desirable responses. This suggests that the influence of power differentials is not limited to racial differences between researchers and participants. There is a need for more research to be conducted on the nature and effects of power differentials between researchers and participants. Further research on the power dynamics that exist within participants' social contexts may be informative as there are indications that a participant's age and gender is likely to have an impact on the collective's response to participation in research.

The narrative approach

The narratives told gave the researcher insight into Hlabisa people's cultural beliefs, norms and experiences. Almost all the informants had, however, never been participants. They therefore had very limited experience to draw from, and this impacted on their ability to provide stories about research participation. The interview questions were also hypothetical in that they mostly asked informants about "other" people and not really about themselves. The hypothetical nature of the questions enabled the informants to be comfortable during the interview. It is possible, however, that informants might have given different responses had the questions been about themselves. Future research into past research participants' experiences with research in general and informed consent specifically, might prove informative.

Conclusion

Despite the exploratory nature of the study, it provided a start for enquiries into cultural conceptions of research and informed consent.

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APPENDIX A: INTERVIEW GUIDE

A. What do you think research is?

- Please tell me about research conducted in Hlabisa?
- I have heard stories that people are not happy when research is conducted...what would you say about this?

B. Suppose a young Hlabisa woman had to be approached for participation in a research study. Please tell me a story about what should happen?

- What should she be told?
- How might she make the decision to participate?
- How important would her family be in making the decision?
- Please tell me about what might happen if she did not consult with anyone?
- Could you please tell me about how people were approached for participation in past research?

C. What makes people participate in research?

- Has the community been happy about what they have got from research?
- Would they like the research to continue?
- How would they like it to be different?

APPENDIX B: TRANSLATED VERSION OF THE INTERVIEW GUIDE

Uhla lwemibuzo

K. Ngombono wakho luyini ucwaningo?

- *Ngicela ungixoxele ngocwaningo oselwenziwe kwaHlabisa?*
- *Sengike ngezwa ukuthi abantu abajabuli uma kwenziwa ucwaningo⏏ungathini wena ngalokhu?*

C. ***Akesithi bekufanele kucelwe owesifazane osemusha wakwaHlabisa ukuthi abeyingxenye yocwaningo. Ngicela ungixoxele ukuthi kufanele kwenzekeni?***

- *Kufanele atshelweni owesifazane?*
- *Angasithatha kanjani isinqumo sokuba yingxenye yocwaningo?*
- *Ungabaluleka kanjani umndeni wakhe ekuthatheni isinqumo?*
- *Ngicela ungixoxele ukuthi kungenzekani uma engabonisani namuntu?*
- *Ngicela ungazise ukuthi abantu bebecelwa kanjani, esikhathini esedlule, ukuthi babeyingxenye yocwaningo?*

I. Yini egqugquzela abantu ukuthi babeyingxenye yocwaningo?

- *Uthokozile yini umphakathi wakwahlabisa ngalokho okuthole kucwaningo?*
- *Bangafisa yini ukuthi luqhubeke ucwaningo?*
- *Bangafisa ukuthi lwehluke kanjani?*

APPENDIX C: STANDARD INTRODUCTION

Greetings and introductions,

You have been identified by some members of the Hlabisa community as one of the people that are influential within the domains that they occupy in the area, and are thus knowledgeable about the community. I would like to interview you about your perceptions of research and informed consent, particularly in relation to research. I am also interested in how you believe the people of Hlabisa might feel about these subjects. The information you provide will be used to ensure that the researcher gains more insight into what Hlabisa people would prefer in terms of research and informed consent. This will involve being interviewed by me. You will be asked questions about your perceptions of research, as well as about Hlabisa people's perceptions of past research. I would also like to know how you feel people should be approached for participation in research. We would also like to hear your opinions with regard to why people agree to participate in research.

The information that you provide will be treated with confidentiality and only my supervisors and myself will have access to it. If you are agreeable, the interview will be tape-recorded so that we can remember the information that you have provided. If you are uncomfortable with the tape recorder, I will take notes. If you agree to be tape-recorded, but feel uncomfortable about the tape-recorder at a later stage, you may switch the tape recorder off. We would appreciate your participation but if you are uncomfortable and feel unable to participate, we will respect your opinion and there will be no negative repercussions.

APPENDIX D: TRANSLATED VERSION OF THE STANDARD INTRODUCTION

Indlela efanayo yokwethula ucwaningo

Sawubona

Ingxenye yamalunga omphakathi wakwahlabisa iphakamise igama lakho phakathi kwamagama abantu ababambe iqhaza emphakathini, futhi abanolwazi ngomphakathi wakwaHlabisa. Ngifisa ukuxoxisana nawe mayelana nemibono yakho ngocwaningo, kanjalo nokunikezwa kwemvume yokuba yingxenye yalokho osuwazisiwe ngakho, ikakhulukazi mayelana nocwaningo. Ngingathokoza ukuzwa ukuthi ukholwa ukuthi abantu bakwaHlbisa babona kanjani mayelana nalemikhakha. Udaba onginikeza lona luzongelekelela ukuthi ngiqonde kangcono ukuthi abantu bakwaHlabisa bafisani mayelana nocwaningo nokunikezwa kwemvume yokuba yingxenye yocwaningo umuntu asaziswe ngalo.

Udaba mayelana nocwaningo kanjalo nokunikezwa kwemvume lungatholakala ngokuthi sixoxisane. Uma uvuma ukuthi sixoxisane, uzobuzwa imibuza mayelana nemibono yakho ngocwaningo, kanjalo nemibono yabantu bakwaHlabisa ngocwaningo oselwedlule. Ngifisa ukwazi ukuthi ubona engathi abantu bangacelwa kanjani ukuthi babeyingxenye yocwaningo. Ngifisa nokuzwa imibono yakho mayelana nokuthi yini eyenza abantu bavume ukuba yingxenye yocwaningo.

Ongitshela khona kuzophathwa ngemfihlo, futhi yimina nalabo abangiphethe kuphela esizokwazi ngokuxoxwe yimi nawe. Uma uvuma ukuxoxisana nami, ingxoxo yethu izoposhwa ukuze sikwazi ukukhumbula okuxoxiwe. Uma ungakhululekile ngesiqophi, ngizothatha amanothi, singasetshenziswa isiqophi. Uma uvuma ukuthi ingxoxo yethu iqoshwe, kepha ubuye ungasakhululeki ngesiqophi kamuva, ungasicima. Singabonga kakhulu uma uvuma ukuba yingxenye yocwaningo kepha uma ungakhululekile, futhi ungafisi ukuba yingxenye yalo, sizowuhlonipha umbono wakho futhi ngeke kube nemiphumela emibi.